Dear President,
Dear Board members,
Dear ADDE members,

We want to give you our best wishes for 2018.

We identified the following recent developments at EU level that could be relevant for the dental dealers in Europe:

1. Public consultation on EU funds in the area of investment, research & innovation, SMEs and single market

The European Commission ("**Commission**") opened a public consultation by which it invites all citizens and organization to contribute ideas for the design of **the next EU long-term budget** (the post-2020 Multiannual Financial Framework).

EU funds in the area of investment, research & innovation, SMEs and single market

The current Multiannual Financial Framework — the EU's long-term budget — runs until the end of 2020. In 2018, the Commission will put forth comprehensive proposals for the post-2020 Multiannual Financial Framework and for the next generation of financial programmes that will receive funding. These programmes/funds provide financial support to hundreds of thousands of beneficiaries, including businesses.

As an integral part of this process the Commission is launching a series of public consultations covering all the major spending areas to gather views from all interested parties on how to make the very most of every euro of the EU budget. You can find the Commission's Reflection Paper on the Future of EU Finances here.

Regarding EU financing for businesses, there are a variety of instruments within the EU to stimulate entrepreneurship and investment to create jobs and growth. The European Fund for Strategic Investments (EFSI), provides an EU guarantee to mobilise investment. It also complements other existing instruments like COSME that make it easier for small and medium-sized enterprises (SMEs) to access finance in all phases of their lifecycle – creation, expansion, or business transfer. Through EU support, businesses have easier access to guarantees, loans and equity capital.

Objective of this public consultation

Prior to making new proposals for the EU's post-2020 Multiannual Financial Framework, a careful assessment of what worked well in the past and what could be improved in the future will be made. This consultation is an integral part of this process and its objective is to collect the views of all interested parties on how to make the most of every euro of the EU budget.

More information on the public consultation can be found here.

If ADDE would be interested to share its views on the EU's long-term budget for issues related to investment, entrepreneurship, research, innovation and SMEs, it can complete the online questionnaire.

Link to the questionnaire: https://ec.europa.eu/eusurvey/runner/MFFpost2020investment

2. Safe products in the EU-Single Market: Commission acts to reinforce trust

On 19 December 2017 the Commission adopted a new proposal for a Regulation on Compliance and Enforcement. The objective of this draft regulation is to strengthen controls by national authorities and customs officers to prevent unsafe products from being sold to European consumers. You can find the draft regulation here.

What does the proposal include?

The draft regulation must help create a fairer internal market for goods, through fostering more cooperation among national market surveillance authorities. It intends to do so, as follows:

- by sharing information about illegal products and ongoing investigations so that authorities can take *effective* action against non-compliant products;
- by helping national authorities improving checks on products entering the EU market;
- by encouraging joint actions by market surveillance authorities from several Member states;
- by consolidating the existing framework for market surveillance activities.

You can find the Commission's press release here.

What will happen next?

The draft regulation follows the co-decision legislative procedure. The draft regulation has now been sent to the European Parliament and Council for adoption. The proposal will go through a first reading by the European Parliament, followed by a first reading of the Council.

Please let us know if ADDE would like to obtain more details about this draft regulation and the impact it may have for dental dealers in the EU.

3. Recent developments regarding harmonised standards

There are two recent developments regarding harmonised standards at EU level.

First, the Commission and the European Standardisation Organisations (ESOs) have launched an Action Plan to improve the publication of harmonised standards (a).

Second, the Commission published an updated list of references of harmonised standards on medical devices, active implantable devices, in vitro diagnostic medical devices, radio equipment and pressure equipment (b).

a. Action Plan to improve the publication of harmonised standards

The Commission and the European Standardisation Organisations (ESOs) launched an action plan to reduce the number of non-cited standards and to improve legislative compliance of harmonised standards during their development.

Why do we have harmonized standards?

In certain EU harmonisation legislation for products, voluntary harmonised standards, developed by the European standardisation organisations (CEN, Cenelec and ETSI), may be used by

manufacturers to demonstrate compliance of their products with applicable essential requirements.

Such harmonised standards confer a presumption of conformity with legally binding requirements after the Commission has published their references in the Official Journal (OJ).

Increase number of non-cited harmonised standards

For the standards system to work to its full potential, it is important that references to harmonised standards in the Official Journal are published in a timely manner. However, in recent years there has been an increase in the number of non-cited harmonised standards.

The Commission, in cooperation with the 3 European Standardisation Organisations (ESOs), CEN, CENELEC and ETSI, have developed an Action Plan aiming to provide both structural solutions to decrease the stock of non-cited harmonised standards, and a more transparent, accountable process for smooth citation in the future.

The medical device sector has been added to the priority list of the Commission and the ESOs in order to increase the citation of harmonised standards.

The press release of the Commission can be found here.
The Action Plan can be found here.

b. Updated list of references of harmonised standards on medical devices, active implantable devices, in vitro diagnostic medical devices, radio equipment and pressure equipment

On 17 November 2017, the Commission published **updated lists of references of harmonised standards on medical devices, active implantable devices, in vitro diagnostic medical devices, radio equipment and pressure equipment**.

New harmonised standards covering the following topics were published for the first time on 17 November 2017:

1. Prosthetics - Structural testing of lower-limb prostheses - Requirements and test methods (EN ISO 10328:2016)
2. Medical devices - Quality management systems - Requirements for regulatory purposes (EN ISO 13485:2016 and EN ISO 13485:2016/AC:2016)
3. Clinical investigation of medical devices for human subjects - Good clinical practice (EN ISO 14155:2011/AC:2011)
4. Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements (EN ISO 15223-1:2016, Corrected version 2017-03)
5. Prosthetics - Testing of ankle-foot devices and foot units - Requirements and test methods (EN ISO 22675:2016)
6. Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment (EN 60601-1-3:2008/A11:2016)
7. Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (EN 60601-1-8:2007/A11:2017)
8. Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical

diagnosis (EN 60601-2-33:2010, EN 60601-2-33:2010/A1:2015 IEC 60601-2-33:2010/A1:2013, EN 60601-2-33:2010/A2:2015 IEC 60601-2-33:2010/A2:2015, EN 60601-2-33:2010/AC:2016-03, EN 60601-2-33:2010/A12:2016)

The press release of the Commission can be found here.
The harmonised standards published by the Commission can be found here.

We hope this information is of any help to you.

We will keep you updated about any developments or opportunities in your field.

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

Best regards,

Sarah

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