ADDE General Secretary
Moosstrasse 2
CH-3073 Gümligen
☏ 0041 (0) 31 952 78 92
🖷 0041 (0) 31 952 76 83
✉ info@adde.info

Newsletter 3/12

Gümligen, September 27, 2012 UW/we

FROM THE PRESIDENT'S DESK

Dear friends,

I hope you have all enjoyed relaxing and pleasant holidays.

Just like too much sun or rain in various parts of Europe, we were sometimes confronted during these holiday months with good or bad news about Europe depending on the region where we stayed.

It was always too much or too little, never enough, both as regards the news and the temperatures and/or humidity. It makes you wonder if the weather also has an uncertain feeling about the European crisis.

Indeed, the crisis did not just come to a halt during the holidays of our politicians, our European institutions or our banking industry.

All things considered it becomes very clear that we have not yet passed through the crisis but that we find ourselves on the threshold of an economy that needs to save while at the same time making sufficient investments on the road back to recovery.
For me it all starts with the profitability of our companies.

Contrary to what is often mentioned in newspaper headlines or quick comments, we are all struggling with a general margin problem, aside from a few exceptions. This discussion deserves a lot more attention than it is currently getting, as business profitability is an absolute must for social welfare and the revival that is so badly needed for our European economy.

Margin is the difference between sales revenues and costs. Our revenue is determined by the sales volume multiplied by the average price. The market, often at international and European level, determines our prices. Only with a clever niche strategy companies can become more price insensitive. This not only requires from all of us continuous alertness and entrepreneurship in order to maintain and further develop the acquired position, but also the resources to invest in research, product and market development. Inadequate cost-effectiveness therefore weighs heavily on the possibilities to reach a niche strategy.

Moreover, in all countries our companies are burdened with an almost endless stream of new taxes and fresh regulations. Their impact on our profitability is rarely discussed. Other social concerns may and should obviously play a part when laying down taxation

policies and regulations, yet it has fatal consequences to almost systematically ignore the profitability of companies. This undermines the short-term profitability as well as the companies' ability to invest and consequently their chances of survival in the long term. Those who want to seriously discuss the future of for instance our public finances and the issue of durable employment without explicitly dealing with business profitability, throw dust in their eyes and mislead public opinion.

All the more reason for us to attend the European forum to steer and guide the regulations for us and our customers in order to avoid impossible situations and continuous pressure on our business.

Our sister organization FIDE has provided us with all information to join the "MDEG" Group together with them and our people in Brussels. MDEG is a group of commissioners of the members of the European Union, industry and other representative stakeholders in the area of medical devices and the implementation of the directives.

This group is an umbrella organization for other study groups in this field; it coordinates and supervises all activities. The MDEG chair belongs to the European Commission. Responsible for this directorate are "Health and Consumers" (= DG Sanco) and the unit B2 "Health Technology and Cosmetics". Mrs Sabine Lecrenier is head of this unit.

In collaboration with our office Contrast in Brussels and our sister organization we will work up this subject and keep you informed accordingly.

As announced in my preface of the previous newsletter we are currently preparing a States General in Brussels where we want to inform all major actors from the European commissions of our needs and requirements.

Together with the Contrast office that will be our "Gatekeeper" towards the European Union as from 2013 – a decision that was made by the Board with general approval during our Board Meeting in Brussels on August 23 – we will organize this while at the same time reinforcing and continuing other activities towards and for the European Union.
We will invite all European decision makers to this event in Brussels to explain all aspects of our dental business. This is also an excellent opportunity for us to invite all dental players within this field. Further news will follow.

So more than ever we must keep our ranks closed and work closely together for the dental future of Europe. This can only be done with your support, your financial resources and your input through your national networks.

I hereby promise you that the Board and myself are committed to use all possible means of ADDE to perform our main task which is being a lobbyist and a support to our dental distributors in all the countries where we are represented.

We know that every euro counts and we will ensure that it is wisely invested in our core business.

You can rely on me and our Board. In return we are counting on your collaboration.

With kind and fraternal regards from

Your president,
Dominique Deschietere

WE CAN'T DIRECT THE WIND
BUT ADJUST THE SAILS!

I have choosen the title of my column just after the last Board meeting in Brussels. In fact the ADDE leadership is in many ways determined to act more and more in lobbying fields. This is not astonishing since one of the important

statutory goals of ADDE is to create best economic and legal conditions for the dental dealer companies to work with good results in a tough market.

However the economic climate in general and particularly in health care areas is not in our hands, but we can "adjust the sails" in order to make the best of it. Thus it is well understood that the ADDE board is focussing on less mandatory norms (or at least more comfortable regulations) for our branch. The business in this field is not an easy one since many other actors try to get a big piece of the pie! Nevertheless what we can do is fighting against the "regulation density", against unneeded prescriptions and norms not only for the dental trade but for the whole dental sector, from the industry via commerce to labs and dentists as end users! Such a perspective asks for teamwork with the various stakeholders when we want to effectually realize a successful lobbying.

And by the way: lobbying has to be understood like a fire engine. You cannot order the fire-extinguishing equipment only when you recognize the glow of a fire. Lobbying needs a continuous commitment. Therefore we better start quickly!

The concept of a coordinated action plan needs to anticipate various "regulation dangers" and must be harmonized between suppliers and en users. Let's go!

Dr. Ulrich Wanner
Secretary general of ADDE

TECHNICAL COMMITTEE

The ADDE TC shall meet in Paris next time (November 28th). The agenda is not yet established, but several projects of legislation are in the EU-"pipeline", such as regulation on e-labelling, the nanotechnology linked to medical devices, unique device identification and more.

Regarding Cone Beam CT-Scanners the re-commendations stated by SEDENTEC, presented by Ed Kolsteeg at the last TC-meeting as valuable and helpful document for stakeholders in the dental branch, have been translated in the mean-time into Italian, Dutch, Hungarian. This document can be ordered free of charge at the ADDE-secretariat by ADDE members.

At the EU-lobbying-event earlier this year, the

ADDE president revealed this problem and gave the documentation to the EU authorities and MEPs.

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The regulation on e-labelling defines the conditions under which instructions for use of certain medical devices may be provided in electronic form instead of in paper based documents. This regulation shall apply from March 1st, 2013. The e-labelling-item is particularly touching the manufacturers. Since however various language require-ments may be difficult to be fulfilled the instructions for use in electronic form shall also be made accessible to the end-users via a website. It may be thus an additional infor-mation channel on websites of dealers desired by suppliers. Nevertheless we make dealers aware of being, in those situations, reliable for correct and complete instructions!

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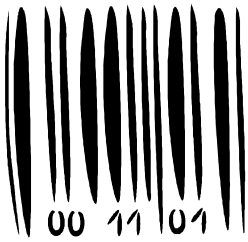
Unique Device Identification, item discussed at the TC-meeting last November already,

becomes again a special theme for health branches:

The US Food and Drug Administration (FDA) had released a proposed rule that most medical devices distributed in the United States carry a unique device identifier (UDI). A UDI is a unique numeric or alphanumeric code that includes a device identifier, which is specific to a device model, and a production identifier, which includes the current production information for that specific device, such as the lot or batch number, the serial number and/or expiration date.



UDI appears in a machine-readable format (regularly barcode, e.g. HIBC-Barcode) on the device label or packaging. A UDI system may help the FDA identify product problems more quickly, better target recalls and improve patient safety.

The European Commission also develops a UDI system to ensure the traceability of medical devices. In the first step the focus will be on the high-risk medical devices (class III and class IIb devices).

THE IRISH REPUBLIC EXPECTS US…

The Annual General Meeting 2013 of ADDE shall take place in Ireland. Pat Bolger invited the ADDE delegates at the last AGM in Sofia to travel next time west in order to visit Ireland – "one hell of a place for adventure" as describes the Irish Tourist office this part of the world.

We don't know AGM-details for the time being, but the date (not yet confirmed) may be April 11-13, 2013. Almost sure is Dublin as meeting place.

There is no doubt, our Irish friends will offer us an exciting programme in a unique adventure surroundings. More details will follow soon, maybe not only in the next Newsletter issue. So, have a look from time to time to our website www.adde.info.

CALENDAR OF ADDE-EVENTS

TC-meeting	28.11.2012	Paris, France
Board-meeting	28.11.2012	Paris, France
EDBC-meeting	28.11.2012	Paris, France

EU/TC-MATTERS

- Ticket machines, household appliances, computer keyboards: any device intended for use by human beings should be not only safe, but also easy to reach and use. Irrespective of the environment in which it is used (work, home, leisure), the underlying ergonomic principales are always the same. These principles have now been summarized for the first time for all applications in a single standard: EN ISO 26800, published in November 2011.

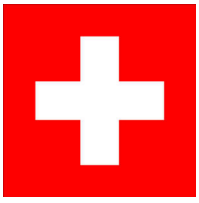
  EN ISO 26800 "Ergonomics – General approach, principles and concepts" serves a generic ergonomics standard

and was developed in order for the essential principles and concepts of ergonomics addressed by other standards to be placed within a common framework. The standard presents generic principles which are of fundamental importance for the design of products. It also explains four concepts which can be referred to for a better understanding of these principles and for their application (see diagram).
The purpose of the standard is to assure the ergonomic design of systems and products by applying the principles and concepts over the entire life cycle.

- **Online submission of proposals for standards**
  With immediate effect, proposals for standards and specifications can be also submitted to DIN online at www.normungsantrag.din.de. Following a brief registration process, the user enters the key aspects of the proposal on a form. DIN then consults the stakeholders to ascertain whether a need exists for the standard or specification concerned. If the proposal meets with a positive response and financing is in place, the work of the project is assigned to a DIN working committee. Proposals can of course be made to DIN in person or by telephone, as before.

SWISS DENTAL EXHIBITION: SUCCESS!

The inquiry results for the Swiss dental exhibition held this spring in Berne reveal a good success. The Swiss dental association

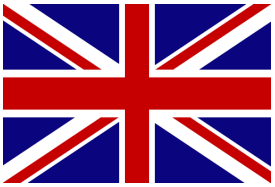


even reports that the number of congressists got the best result ever. And of course this had an impact on visitors even if this time the representatives and delegates from the dental lab association were quite a bit missing.

The exhibition place Berne, in the center of the country, offers an easy access by trains from almost all corners of Switzerland. Berne may also be the exhibition place in 2014 according to the announcement made by the Swiss dental trade association.

NEW BDTA RESEARCH REVEALS PATIENTS REALLY DO WANT TO TALK TO THEIR DENTIST

New research from the British Dental Trade Association (BDTA) reveals a significant proportion of patients (20%) are "warm" to a variety of elective treatments although currently awareness of available treatments is quite low.



The BDTA commissioned Bray Leino, one of the UK's leading market research agencies within heathcare, to conduct the research amongst 1'500 members of the general public and found that patients would welcome the opportunity to spend more time talking to their dentist about available treatments and their pros and cons to help them make more informed treatment choices.

The research confirms that patients have a very high degree of trust in their dentist, even greater than in their doctor, with 88% of all respondents satisfied (46% extremely happy and 41,8% fairly happy) with the level of service they receive.

Not only are dentists highly trusted, but by far the majority of patients, both NHS and private alike, found their current dentist by word of mouth. Similarly they would choose a personal recommendation from family and friends over any other means of finding a new dentist if they needed to (67% private : 65% NHS). This is good news for dental practices enabling them to develop an approach to encourage recommendations knowing they will be helping people find a dentist through their preferred route.

Unsurprisingly, fear was found to be a compelling inhibitor, particularly amongst infrequent attenders, however for many patients (59%) a "friendly and relaxing environment" helps them to overcome this barrier.

Together with trustworthiness, "value for money" was cited as the most motivating of all messages for infrequent patients. In today's era of austerity with rising household bills and reduced disposable income, clearly priced personal treatment plans will resonate well with patients.

Based on these findings the BDTA, in collaboration with the UK Dental Association Alliance, has produced the "Top Ten Insights to Successfully Grow Your Dental Practice", download your free copy at: www.dentalalliance.org.uk.

DIRECTIVE ON TOOTH WHITENING PRODUCTS

This EU directive concerning cosmetic products and particularly tooth whitening and bleaching products had entered into force on November 18th, 2011. EU-member states will have to apply the Directive provisions from October 31st, 2012.

The Council of European dentists (CED) has set up guidelines to interpret and implement this directive. The full text of those guidelines is available under forms/documents of the ADDE website.

EVENTS

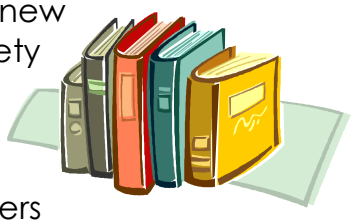
The worldwide association of dentists, the FDI, shall organize next year its annual world dental congress from 28th to 31st August 2013 in Instanbul. The Congress linked to the statutory meetings as well as the dental exhibition will complete the programme. The city of Istanbul has many things to offer for everyone and guarantees a very good attendance from dentists' side.

For more information: www.fdi2013istanbul.org.

PUBLICATIONS

The new German Product Safety Act

In this guide, Thomas Wilrich provides a commentary on the new German Product Safety Act (ProdSG). The focus of the guide lies upon the duties of manufacturers, importers and distributors set out in the act. The guide also contains numerous checklists and aids to selection for practical use. Beuth Verlag, 2012, 360 pages, ISBN 978-3-410-22325-2, €48 (printed or e-book).



Next ADDE Newsletter issue:

17th December 2012

Please send articles to the ADDE General Secretariat for publication **till December 1st**. Thanks.