European Parliament adopts new medical device regulations

By DTI

BRUSSELS, Belgium: The European Parliament has voted to implement two new regulations concerning medical devices with the aim of improving safety in medicine and dentistry. The regulations were proposed in 2012 by the European Commission and experienced several delays before being officially endorsed earlier this month. They will be applied after a transitional period of three years from publication for medical devices and five years for in vitro diagnostic medical devices. Publication is expected to take place shortly in the Official Journal of the European Union.

Though the rules regarding the safety and performance of medical devices were standardised throughout the EU in the 1990s, significant progress in technology rendered these standards in need of updating. In addition, manufacturers could interpret the three existing directives on medical devices—which will be replaced by these regulations—in different ways, thereby creating inconsistencies in adherence to these rules. The new regulations aim to remedy this by ensuring that this progress and innovation continue in a way that is beneficial to the safety of all involved. At the same time, smaller and medium-sized companies are facing the challenge of meeting the new requirements for clinical data, new legal requirements and certifications for all dental products.

Some of the main elements of the regulations include:
- Stricter measures on the quality, safety and performance of devices released into the marketplace, with a particular emphasis on perceived high-risk devices
- A scrutiny mechanism for Class III implants and Class IIb active products
- The introduction of a comprehensive database for medical devices sold in the EU (EUDAMED), to be set up by 2020 at the latest
- Higher requirements for clinical data and technical documentation before and after placement of the respective product on the market
- A universal device identification system that will permit medical devices to be traced more easily
- An implant card that will be given to patients so that they, along with medical professionals, have access to information about any implants they receive
- A set of guidelines for providing appropriate financial recompense to patients for faulty products (the payment will vary according to the risk class and type of device, as well as the size of the company that manufactures the device, and will ideally expedite the remunerative process)
- Guidelines for manufacturers of substances that are carcinogenic, mutagenic or toxic for reproduction, as well as substances that can disrupt the endocrine system, to provide alternative and less harmful products.

The regulations will be applicable in each of the EU member states and aim to provide a clearer framework regarding device standards to patients, professionals, and relevant domestic and international regulatory bodies. A Medical Device Coordination Group, formed of experts from member states and chaired by the European Commission, will be established to help organise and enforce the correct implementation of these regulations.

In addition, conformity assessment procedures by notified bodies—intra-national organisations that evaluate medium- and high-risk devices—will continue to be performed through joint assessments conducted with the assistance of other member states.
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Continuing acquisition will be a strategy for larger key competitors

An interview with Jeff Wong, Strategic Analyst Manager at iData

The ever-progressing digitalisation, changing regulations and a tendency towards mergers are currently shaping the dental industry. At the International Dental Show (IDS) in Cologne, Dental Tribune met with Jeff Wong, Strategic Analyst Manager at international medical market research and consulting firm iData, to talk about how—major and emerging—competitors have reacted to these trends.

Dental Tribune: Digitalisation is one of the main trends that is changing the industry. Other than that, what developments are dominating the dental market?

Jeff Wong: Yes, digitalisation is still the up-and-coming trend and everybody is trying to get into that market now. On the product side, I would say it is 3-D printing and intra-oral scanning. Three or four years ago, there was only a handful of competitors in both of those areas. This year at IDS, almost everybody was presenting some new product in these fields—knowing how fast these markets develop, everybody wants to participate.

What consequences will this have for the market in general?

Especially in these two areas, where the level of imitation is high, with so many competitors, it will definitely start diluting the market shares among the existing companies. However, if these participants start focusing on specific regions or niche audiences, I think there will still be a great deal of benefit.

What about the recent merger trend—is that something we will see more of in the future?

From what we have seen in other industries, we definitely predict that the trend will continue. Of course, there will always be a couple of smaller companies that will end up becoming fairly large themselves and remain independent. However, we expect that many of the successful emerging companies will be acquired at some point. One advantage that the larger competitors have is the amount of resources they have. They can always stay ahead of the curve if they see somebody come to the market with something unique, they have the resources to quickly develop a product of their own.

What role do the emerging markets play? What regions will become more significant in the future?

Regarding digital dentistry, I would say much of the development is linked to implantology and prosthetics. The key countries where these areas are big as well are Brazil and Italy. Even though the penetration of digital dentistry might be relatively higher in those areas compared with others, I would say they have the greatest opportunities for growth.

What are the main trends in implantology?

In terms of implants, dozens of new companies are popping up every year, but many are also either acquired or close down. There are definitely certain regions that are experiencing a great deal of growth, for example many Asian countries. At the same time, traditional markets such as Italy, Brazil and the US are doing very well. These markets are well penetrated at this point, so in terms of market growth it will definitely slow down. However, there is still substantial growth opportunity for the lower-priced competitors, while the traditional premium brands will see considerable competition from other markets.

Do you think this will lead to these companies buying local competitors? Or what will their strategy to succeed be?

I think the strategy of most of the larger key competitors will be continuing acquisition. However, the strategy of some of the larger regional companies, for example in Brazil, is to continue going and to expand their global presence instead of being acquired.

In addition, many of the current key participants—with the regulatory environment changing from country to country—are being forced to acquire new companies in order to be able to operate in the region.

So, you are saying that larger companies are looking for smaller businesses to acquire in order to bring new technology to market?

Not only on the technology side, but also to compete on the pricing level as well.

In the current political climate, the Chairman of the Association of the German Dental Industry has issued a warning about protectionism and trade barriers. What are companies doing in this regard?

At this stage, I think, companies are mainly waiting to see what will happen. Nevertheless, in light of what is happening in other industries regarding the whole Brexit issue—for example, European Union chiefs have warned airlines, including easyJet and Ryanair, to relocate their headquarters to the EU if they wish to continue their routes within continental Europe after the Brexit—if that can happen in the airline industry, who is to say it cannot happen in the dental industry? Again, for example in Mexico, which has a major dental tourism industry, if that is going to be affected in terms of procedural volumes, it is definitely going to affect the dental manufacturers as well.

Thank you very much for the interview.