Analysis of the survey on the EU Medical Devices Regulation

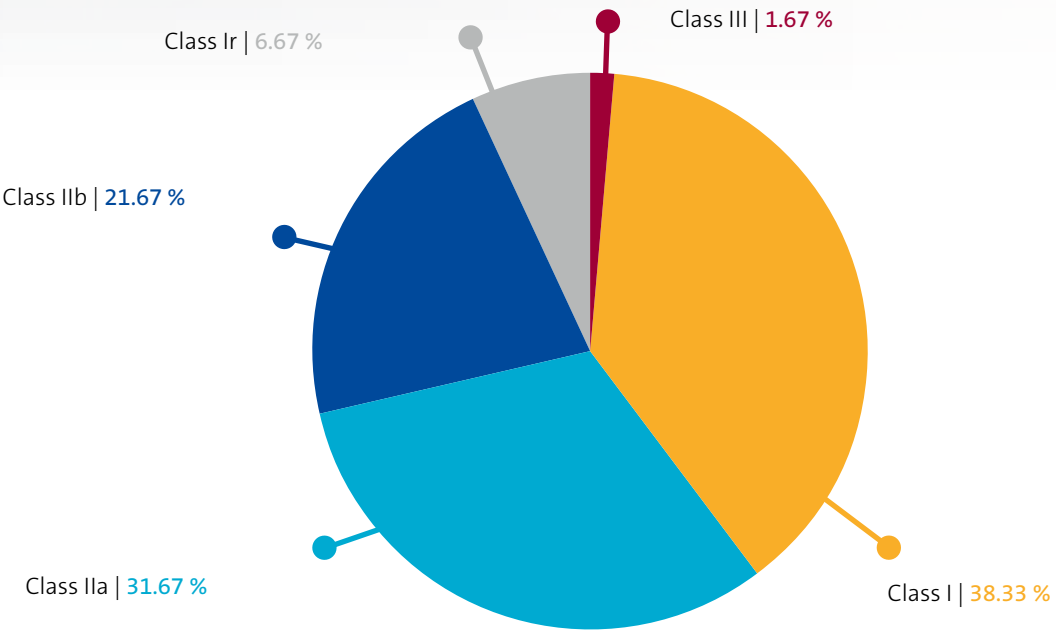
Dental companies to make changes to their product range

The EU's Medical Device Directive (MDR) will have a major impact on the dental industry, on dentists and of course on patients. According to a confidential survey conducted for the BDIZ EDI at the end of 2019 by the law firm of Ratajczak & Partner, more than half of the participating dental companies plan to make changes to their product range. Almost half plan to take products off the market. Although the survey was carried out before the EU Commission extended the transitional period by one year on account of the coronavirus pandemic, this will do nothing to assuage the prevailing pessimism when it comes to the MDR.

The reasons given by the participants included: the red tape and high expenses associated with the clinical evaluation and clinical trials, administration, (re-) certification, plus special efforts for product-specific requirements. The BDIZ EDI is afraid that despite the one-year extension, many products will be discontinued, something that will have a significant impact on the dental sector.

The survey was carried out anonymously. Participants included 24 dental companies that are active nationally and internationally; a third of them have been present on the market for more than 20 years, and half of them had annual revenues of between 5 and 20 million euros in 2018 in Germany alone. The majority of participants manufacture medical products, either exclusively or as more than 90 per cent of their output. Class IIa and IIb products make up a large part of their production (Fig. 1).

1 I What are the product classes in which your company manufactures medical devices? (Multiple answers were possible.)



Almost 57 percent of respondents assume that the MDR will affect the classification of their own products, especially class I and IIa products. More than half of respondents indicate that they will have to modify their product selection in response to the MDR. Only 5 per cent of them unequivocally deny that the changes will restrict their product range, whereas 46 per cent say they will take certain products off the market completely.

Products that are no longer considered profitable, according to the majority of respondents, will not only disappear from the market but will also fail to be replaced by equivalent products. A significant percentage of respondents also predict effects on non-European markets (Fig. 2).

Supply bottlenecks expected

Ultimately, the MDR is seen by market participants and observers as a brake on innovation that will not fail to affect dental practices as well. Half of respondents expect restrictions in available supplies of dental medical devices. And 41 per cent of respondents go so far as to say that patient care will suffer as a result of the MDR. Spokespersons for the dental industry recommend dental practices to prepare for supply bottlenecks, with class I and IIa products expected to be particularly affected. Class Ir devices, by contrast, play only a subordinate role in terms of these dreaded bottlenecks (Fig. 3).

A full 80 per cent of respondents expect the prices for existing and new products to increase, by an expected amount of 22 per cent. They expect pressure to cut cost as a result of the MDR, but not to the extent of dismissing employees or going out of business. The situation may present itself in a different light for the many small manufacturers of class 1r products, as BDIZ EDI legal adviser *Professor Thomas Ratajczak* believes: "Here it is to be expected that the span between certification cost and profits will force quite a few to either sell their businesses or to cease operation."

If the transitional period for certification expires as planned in May 2021 (even though this date has been moved back from the original May 2020), this will inevitably result in reductions to the dental industry's product range, which will ultimately become a problem for dentists and their patients. A full 90 per cent of respondents consider a further extension of the transitional periods to be of vital importance; 30 per cent consider an extension of 24 months to be necessary (Fig. 4).

The survey results have ben published in EDI Journal 1/2020, which BDIZ EDI members can download from the "publication" area of www.bdizedi.org. ■

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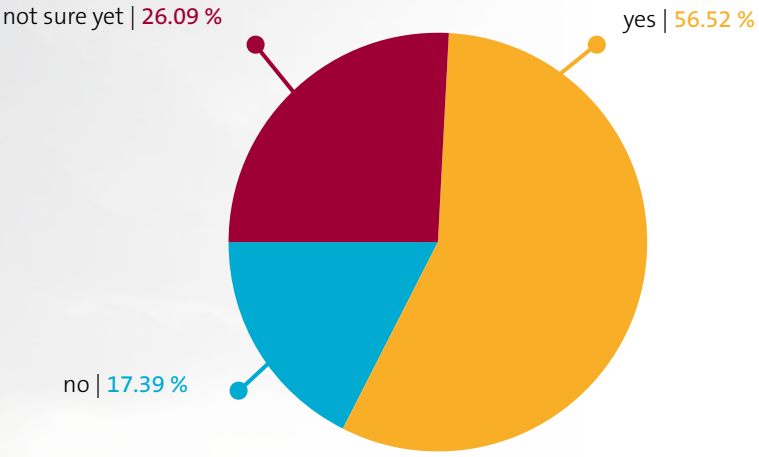
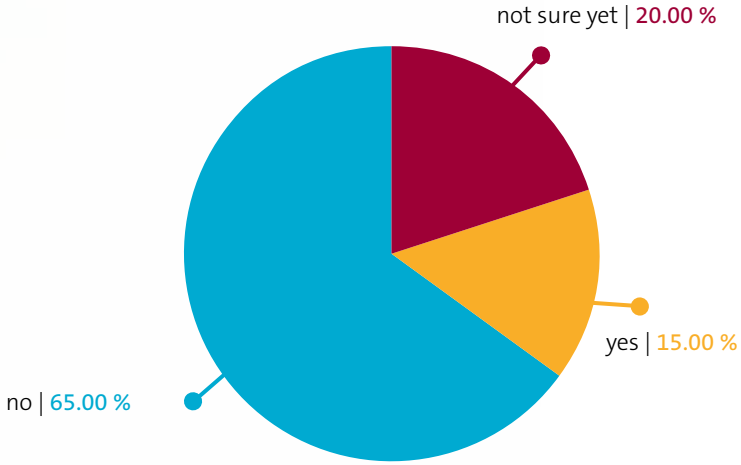
2 I Will your product range change in response to the MDR?



3 I Are the discontinued products to be replaced by alternative (equivalent) products?



4 I Have you been able to (re-)certify any products at all?