Electronic instructions for use of medical devices (eIFU)

Position paper of FIDE (Federation of the European Dental Industry)

I. About FIDE

FIDE was founded in 1957 and has its headquarters in Cologne (Germany). The federation includes 10 national federations of the dental industry with a total of around 550 companies. FIDE represents the common interests of European dental industry companies at a technical and political level in dealing with ministries, authorities, associations and other organisations nationally and internationally.

II. Introduction, current position

The requirements of the instructions for use of medical devices (IFU) are defined in the European Medical Devices Regulation (MDR), which is applicable since 26.05.2021. The manufacturer must always enclose the IFU in paper form with the product. However, the EU Regulation on electronic instructions for use of medical devices (eIFU) from 09.03.2012 (Regulation No. 207/2012) permits an electronic version in place of a paper version in certain cases. This essentially applies to implantable products, fixed installed devices and products with integrated display.

The EU Commission published a draft for revision of Regulation 207/2012 in May 2021. It did not, however, feel it was in the position to submit the regulation to an urgently needed, general revision due to a lack of resources. The scope of application has only been minimally extended. The wide use of electronic instructions for use and the advantage of the opportunities provided by them continues to be denied to all involved.

Consequently, for many medical devices the instructions for use must also in future continue to be prepared in paper form. They must also then be prepared in up to 27 official EU languages.

III. Reasons for extension of the scope of applications

The current narrow limitation of the scope of applications to the above-named products is not in keeping with the ongoing digital transformation. The safety of medical devices would not be affected by providing an eIFU. Furthermore, the restrictive interpretation by the European Commission is contrary to its own sustainability strategy with regard to the Green Deal.

FIDE therefore regards it as necessary, to revise the draft presented by the EU Commission and to approve provision of an eIFU for all medical devices, which are utilised or applied by professional users.

The following reasons support this view:

1. Superior user-friendliness of digital applications

Technological advances in the last ten years have led to a significant increase in the use of products in digital form instead of analogue form. For the great majority of the population the use of digital media has become standard practice, without doubt habituation has occurred in digital use. Almost 90% of the population in the European Union now use the internet. It is indispensible in the daily routine of the working population. The use of digital media is self-evident for specialists in the medical technical field. They require access to a computer and other electronic resources for completing their daily tasks. Moreover, skilled workers, in particular, have specific knowledge and experiences in their medical discipline and are well qualified for handling medical devices.

2. Risk management ensures increased safety

The draft of the regulation stipulates for all named products, that an electronic instructions for use is only permissible following a thorough and documented risk analysis by the manufacturer. A risk management system must be established, documented, applied and maintained in accordance with Article 10 Paragraph 2 of the MDR and is a central requirement of the MDR. In this way, the manufacturer ensures that the risks arising from medical devices are known, controlled and acceptable in comparison to the benefits. If this is not the case, the risk assessment of the manufacturer would reveal that for certain products a paper version is nevertheless required. This would achieve the objective of the regulation in a much more targeted way in comparison to the blanket exclusions.

3. Professional users favour the eIFU

In the dental industry, an ever-increasing number of professional users see many advantages of an eIFU compared to the conventional paper version. They expressly want eIFUs only and also inform manufacturers about this desire.

This is related to the fact that paper versions are not read in full, but specific statements in the text when looking for the required relevant information. This is not a problem with eIFUs. The user enters the term in question in the search function and immediately receives the required information.

The eIFU is very important in training sessions about the correct use of a medical device. Different end users can be effectively trained at the same time, but this is hardly possible using a printed version. eIFUs can provide other specific information required by the user, e.g. basic information regarding the function of the product, product comparisons, integration of animations in an eIFU or enlargement of details to improve the legibility.

Advantages that a paper form could provide are unclear.

4. eIFU as a contribution to the EU sustainability strategy

The sustainability strategy of the EU is aimed at improving the quality of life, protecting the environment and climate, as well as saving energy. Aspects such as dispensing with the use of paper copies and concentrating on electronic versions would be in line with the requirements of this strategy. In contrast, paper copies counteract the objective of the EU sustainability strategy. This not only relates to the paper itself but also the associated energy costs required and the savings with regard to millions of litres of waste water.

5. Contribution of the medical technical industry to the conservation of resources

Based on the initiative of its German VDDI member association, FIDE used the discussion as an opportunity to perform a survey of around 200 member companies organised in VDDI about savings, which would be made possible by changing from paper copies to eIFUs. The results delivered by mainly small and medium-sized companies are remarkable: on average a company in the dental industry requires 18 tonnes of paper per year for printing instructions for use alone.

Projected onto the whole of the dental industry in Germany, the paper usage therefore amounts to a minimum of 3,600 tonnes per year. These sobering figures gain even greater significance, however, if it's taken into consideration that for every tonne of paper about 10 trees have to be felled. It follows then that the dental industry alone requires 36,000 trees per year for the printing of instructions for use. Furthermore, it should be taken into consideration that other medical technical fields also use paper for their instructions for use, and the dental industry only has a share of just under 10% of the entire medical technical industry.

In addition, the paper industry is one of the most energy-intensive industries. Although it considerably reduced its CO2 emissions in recent years, in 2018 the industry still emitted 610 kg CO2 per tonne of paper. With regard to the dental industry and possible savings of CO2 emissions, dispensing with the use of paper copies would mean that about 2,200 tonnes of CO2 could be avoided comparatively easily.

6. No concerns about a lack of product safety

From the FIDE's point of view there is no concern that instructions for use in paper form are more readily available for users than eIFUs. The opposite is more likely to be the case. Paper copies can be misplaced, overlooked or even inadvertently thrown away by the user. They may also even not have been included with the product.

In 2012, when Regulation 207/2012 was adopted, nationwide internet coverage was still a big problem. It was therefore logical at the time to initially approve an eIFU only for a limited number of medical products.
Today, however, the situation is completely different. Professional users and healthcare facilities have access to online information at any time thanks to more stable internet connections, so that accessing eIFUs as needed is no longer a particular challenge. eIFUs provided online can also be accessed anywhere at any time using mobile devices or installed computers.
This development has made people less willing to organise storage of paper copies. The possibility of paper instructions not being available may now be considerably higher than failure of the internet connection.

In this respect, eIFUs offer clear advantages compared with paper versions in terms of safe use of the product by the professional user, as they are available or accessible at any time.

7. Advantages of an eIFU compared with paper copies

Paper copies are no longer in keeping with the times and are resource-intensive, not only against the background of digitisation, but also for ecological reasons. Electronic instructions for use have considerable benefits such as currentness, quick availability and user-friendliness, as they can be quickly adapted to user-specific requirements (language version, text size, video explanations, illustrations, colour highlights, specific search entries etc.). They therefore have a higher degree of usability for the user. If a medical device is brought onto the market, it is equipped with the latest instructions for use – for the majority of products in printed form.

An eIFU is also more practical than the paper copy if the instructions for use are updated by the manufacturer. Users only receive the updated instructions for use in paper form if they order a new, identical medical device. If the instructions for use can and may be provided over the internet, users always have access to the new, updated instructions for use.

IV. Conclusion

Digitisation is progressing relentlessly and affects all aspects of life. The medical devices industry should, therefore, also be able to profit from this development.

At the EU Commission resources should be utilised and, if necessary, created to enable the conditions for fundamental revision of Regulation 207/2012.

With regard to the EU sustainability strategy it is crucial that the EU Commission also puts their theoretical approach into practice, in particular if measures that conserve resources

only have benefits for all concerned. Otherwise acceptance and credibility will fast disappear.

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