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SPECTARIS-Position

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Implementing Act On Electronic Instructions For Use

The European Commission is currently discussing the revision of Commission Regulation 207/2012 on electronic instructions for use (e-IFU) of medical devices. **SPECTARIS highly welcomes** the Commission`s and Member States` **intentions to enhance the use of instructions for use in electronic** instead of paper **form**.

The current legislation limits the use of e-IFU for devices intended for the exclusive use by professional users *as well as* to a small list of specific (high risk) devices and further conditions. Limiting the scope to a list of specific devices, however, does not allow for future developments and innovations to be included without regular and constant updates of the regulation. A list of specific devices also raises difficult questions and justifications for why to include some devices to the list and leave out others. Therefore SPECTARIS recommends a stepped approach:

Step 1: Distinguish between professional and lay users

In a first step clarify the user. **If the device is intended for a professional user the manufacturer may provide instructions for use in electronic form – regardless of the risk class or type of the device.**

The internet world stats show that over 90% of the population within the European Union uses the internet (stats from March 2019). Already lay users today use the internet and electronic devices on a regular basis. For professionals it goes without saying that they have access to computers and other electronic resources in their working environment and use these on a daily basis. In addition, professionals, in particular, have specific knowledge and experience in their medical discipline and are well trained for the use of medical devices. **It can therefore well be presumed that professionals in general have access, knowledge and experience to use e-IFU so that devices intended for their use should be provided with e-IFU.**

Step 2: Consider the digital era

In a second step consider developments due to the digital era. Although it is harder to determine the level of access to, as well as the knowledge and experience of lay users with the internet and electronic devices,

many lay users today are familiar with the use of e-IFU, too. Also, more digital products such as software and medical apps continue to evolve and develop. Therefore, additional criteria to allow the use of e-IFU in specific circumstances should be determined in order to address this continued development. These criteria should e.g. take the following questions related to characteristics of the lay user and/or device and how it is used into consideration:

- Does the typical lay user of the medical device have access to the internet?
- Is the typical lay user of the medical device familiar with the use of the internet and electronic devices?
- Is the typical lay user trained (e.g. by a professional prior to the first use of the medical device and/or due to continued use of the device)?
- Does the use of the device itself require the use of the internet and/or an electronic device? (eg. medical software, medical apps)

Benefits of e-IFU

There are multiple benefits for using e-IFU, especially for professionals:

Enhanced Distribution Of Up-To-Date Information

Instructions for use (IFU) contain e.g. information to ensure the safe use and application of the related device. Other than printed information on paper, **electronic information can easily be modified and updated on a regular basis.** Regular updates of information are often necessary e.g for reusable devices because the processes for allowing reuse frequently change. **Information provided in e-IFU is most current** and can be disseminated quickly other than information provided on paper.

Enhanced Availability

Electronic information can be **stored in** only **one place** but be **retrieved** through different electronic means **in different (working) places at any given time – possibly even prior to and independent of the delivery of the medical device** which may be time efficient and beneficial for answering beforehand questions. Enhanced availability is, for professionals in particular, very important as their working places e.g in hospitals often vary, and quick availability of information may be crucial. Paper, however, stores information on one device only and needs to be carried along to be accessible in different places and at different times.

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Enhanced Utility

Other than paper, e-IFU can enable and **adapt to user specific needs** through a variety of tools available: **information is searchable** and thus allows the user to quickly identify the specific information needed. **Text may be enlarged** which enhances legibility. E-IFU allow for **colorings, illustrations and videos to be embedded** that contribute to a better understanding of the information provided. Electronic Information can be projected and **easily used in different ways as needed.**

Enhanced Accessibility

Easier dissemination and storage of electronic information enhance its accessibility. Possibilities to **provide information in a variety of languages** also increase the accessibility to the information and contribute to a better understanding of the information. In addition, e-IFU may facilitate the implementation of specific standards to enhance accessibility for people with special needs (e.g. ISO 14289-1:2016).

Enhanced Sustainability

Paper IFU increase paper waste and have an impact on the size of its packaging as well as its shipping weight. The following example shows the negative impact of paper IFU on the environment and costs: paper waste *per reusable surgical instrument* is estimated to 70.000 kg per year with estimated printing costs between 3 to 4.5 Mio Euro. **E-IFU considerably reduce these negative impacts and enhance sustainability.**

E-IFU in other jurisdictions

Numerous countries allow for e-IFU that are intended for professional users:

In **Australia**, IFU for medical devices intended for use by professional users only, may be undertaken electronically, either online through a manufacturer's website or via other electronic means. For detailed information please refer to: https://www.tga.gov.au/publication/electronic-instructions-use-eifu

In **Canada**, manufacturers may provide information for devices that are not sold to the general public as downloadable from the internet and/or on electronic data storage devices, such as compact disc, digital video disc or universal serial bus (USB) flash drive (see section 21 of the medical devices regulation, file No. 15-107097-797, dated: 26-Jun-2015).

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Taking into account the significant advances in information technologies, regulation in **USA** (Section 206 of Medical Device User Fee and Modernization Act (MDUFMA)) authorizes the use of electronic labeling, rather than the traditional paper labeling, under specified circumstances. Distributors of prescription devices who intend those devices to be used within the confines of a health care facility may provide labeling for those devices solely in electronic form, so long as they afford users the opportunity to request the labeling in paper form and promptly provide such labeling to requestors without additional cost.

Rules for e-IFU also exist in **Brasil** (Normative Instruction – IN No. 4, dated: 15-Jun-2012) that establish requirements for providing instructions for use of healthcare products used by qualified professionals or in healthcare service environments in non-printed formats.

In **Serbia** manufacturer may provide instructions for use in electronic form instead of in paper form if healthcare professionals use the medical device and the accompanying equipment (Official Gazette of RS, No. 105/2017, Article 93).

Saudi Arabia requires that IFU be provided in paper format where the device is intended for the use by lay persons (MDS-G10: Guidance On Labelling Requirements For Medical Devices, dated: 18-Jan-2015).

Conclusion

SPECTARIS encourages the Commission and Member States to enhance the use of e-IFU – in particular where they are intended for professional users. In this respect e-IFU are already successfully in use – limited in Europe and to a broader extent in other jurisdictions worldwide. E-IFU have a positive effect on the environment but most of all, users greatly benefit from e-IFU as they allow quick and up to date information that can be used and accessed according to individual needs.

SPECTARIS is the German industry association for the high-tech medium-sized business sector and representative body in the areas of medical technology, consumer optics, analytical, bio and laboratory technology as well as photonics. Innovation and growth characterize the different industry sectors and their 300,000 strong work force. Technologies developed here are used in almost all branches of industry, making them an important motor for the German economy. SPECTARIS pools the interests of around 400 member companies from Germany.