Position Paper: e-IFU for medical devices

Referring to the attempt of the European Commission to revise the COMMISSION REGULATION (EU) No 207/2012 on electronic instructions for use of medical devices MedicalMountains welcomes this approach and wishes to provide some facts in order to support the revision process.

MedicalMountains is encouraging the European Commission to widen the scope of (EU) regulation 207/2012 and to allow the implementation and the use of e-IFUs also for further medical devices.

Making e-IFUs available for more products than listed in (EU) regulation 207/2012 would only be indicated for products that are intended to be used only by professionals. Most of the manufacturers MedicalMountains is representing are producing well established medical devices with a long clinical history. We are talking about non-high sophisticated reusable surgical instruments for a variety of surgical procedures.

Provided the fact that these instruments are marketed all over Europe and the IFU has to translated into all relevant languages the printed paper IFU might weight heavier than the instrument itself and might request a bigger packaging.

Different other countries have already adopted the ideas of e-IFUs for products other than specified in (EU) regulation 207/2012. Under certain conditions the manufacturers have the possibility to staff their medical devices for professional use with electronic instructions for use.

The following aspects in terms of electronic IFUs are not new and already communicated partwise in (EU) regulation 207/2012 as well as by pressure and expert groups.

1. Less paper for a better environment

In many places there are a lot of discussions in terms of reducing paperwork everywhere. Just only to refer to industry 4.0 where complete manufacturing processes will be controlled and performed without using any paperwork.

In order to provide e-IFUs instead of printed versions will reduce the yearly demand of valuable wood and energy.

Eliminating the paper for each product in question will also make smaller packaging systems possible. Also this option reduces the volumes on packaging materials which consists out of plastic materials or as well paper in the shape of carton materials.

As each medical device needs an IFU an end-user may which may order e. g. several identical devices will only need one IFU. As he gets a bunch of IFUs only a few will be kept and the rest will probably be discarded as being redundant.

Smaller packages with less weight for each SKU can help also reducing the energy input for the transportation since the limited space in transport container can be used more efficiently and less weight reduces the consumption of fuel and other energies.

Within the context of the current discussions of environment protection we believe that these facts are a not neglectable and are touching well known European Regulations in terms of raw material and energy waste.

2. Current end-user information

When a medical device is placed on the market it is equipped with the most current IFU, for most devices in a printed version.

In case the IFU is revised by the manufacturer the end-user only receives this IFU with a new revision when he orders a new identical medical device.

Provided the fact that the IFU can be made available via internet the end-user will always have access to the new IFU.

3. Improved disposability ratio

The disposability of e-IFUs is much better for the end-user than having the IFU in a printed version. The paper IFU might be in many cases not with the device. Medical devices are running through reprocessing processes and will afterwards be stored in e. g. a sterile container. Other medical devices are located in a sterile environment where paper work is not suitable at all.

Having this in mind any separated paperwork can get misplaced or accidentally discarded.

Since physicians in hospitals or offices nowadays do have access to online information and operating rooms are fully integrated in networks the accessibility of e-IFUs does not pose any bigger challenges.

Within a thoroughly performed risk analyses the manufacturer will evaluate the advantages and disadvantages as well as the associated potential risks for each particular medical device and will decide how to develop the supply strategy in terms of the IFUs.

Online e-IFU are accessible from nearly everywhere with handheld devices or installed computers.

A foreign professional working e. g. temporarily in a country with another language will have the advantage of accessing the e-IFU in its mother language if the local health care faculty only has a paper IFU with the local language.

4. Improved fitness for use

Training is a very important aspect in terms of the intended use of all kind of medical devices. A training for different end-users can be effectively performed using the electronic version of an IFU. With paperwork it will be much more difficult to reach a bigger audience.

There is furthermore the possibility for an end-user to get information about medical devices in order to get basic information about the functionality and to compare the particular products.

Within this context an e-IFU provides the possibility to switch between the different sections in order to find the appropriate information either when performing a training or when doing e. g. the set-up during the installation of a new medical device. By the way using a paper IFU is much more time consuming.

It is further possible to have animations within an e-IFU in order to visualize and describe complex interrelations. In parallel all details can be zoomed in to improve to enhance the readability.

Establishing e-IFUs for more medical devices than specified in (EU) regulation 207/2012 will also be a further module towards the aimed goal called E-Health.