Introduction to MEDDEV 2.1/6 Guidelines

Standalone software used for medical purposes have been defined as medical devices for some years. The European Commission has adopted a guide to manufacturers of standalone software that describes the criteria for whether a product should be CE-marked or not. A basic rule is that the system must be CE-marked if the manufacturer has described the system as having a medical purpose. As users, we should then expect the manufacturer to have taken into account patient risk and patient benefit when designing the system.

In January 2012, the European Commission adopted a set of guidelines for software for medical purposes. The background is the revised Medical Device Directive 2007/47 EC, which makes clear that standalone software with a medical purpose are medical devices and therefore subject to the medical device directives.

Because the software has an "intangible nature" the application of the requirements in the directives is not always entirely clear. Work to prepare a guide began on a Swedish initiative in 2009 and was initially led by the MPA. Later, the Commission directed the work and the guide has been developed by a working group with representatives of various agencies and industry bodies. On the Swedish side, the MPA and the industry organization Swedish Medtech actively participated in the working group.

The result is the document "MEDDEV 2.1 / 6 Guidelines on the classification of standalone software used in healthcare within the regulatory framework of medical devices"[1], with definitions, eligibility criteria, decision trees and examples. Some of the challenges for the working group have been;

- The introduction of qualification criteria in addition to those provided in the definition of a medical device.
- What functions can be considered to have a "medical purpose"?
- How to distinguish between software subject to the regulatory framework for in vitro diagnostic devices (IVD), 98/79/EC and for general medical devices (MDD) 93/42/EEC.
- Software available via the Internet.
- An appropriate level of division of systems into modules.
- To develop appropriate product examples.

Due to the rapid development in the area and the expected reactions from the market, the European Commission has suggested the working group continue immediately with a revision of the guidelines.

Comments on some of the issues in the guide that need to be addressed further are presented below.

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[1] http://ec.europa.eu/health/medical-devices/documents/guidelines/index_en.htm

When is a standalone software program to be considered a medical device?

Standalone software may qualify as a medical device on its own merits and is therefore subject to the medical device regulations. When will the software then be considered to be a medical device?

A medical device must have a medical purpose, intended to benefit the patient. This is the case if the manufacturer has specified and described the product such that it can be regarded as having one or more of the purposes described in the definition in Article 1of directive 93/42/EEC on medical devices:

> *'medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:*
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> *— diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,*
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> *— investigation, replacement or modification of the anatomy or of a physiological process,*
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> *— control of conception,*
>
> *and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;*

It is important to remember that a product does not qualify as a medical device merely through its name. Concepts such as "decision support systems", "middleware", "electronic patient records" are a good start, but they are too unspecific to provide enough guidance. For example, whether an electronic health record system is a medical device depends on how the manufacturer has described the system, in terms as defined above. The intended use of the system must therefore include the patient benefit.

If a manufacturer describes a software product in such a way that it can be regarded as a medical device, it must be CE marked under the medical device regulations. A user should then expect the manufacturer to have taken into account patient risk and patient benefit when designing the system. This can be seen in the risk management process and in the post-market follow-up of experience from products in use.

If a manufacturer only describes his system in general administrative / technical terms, this cannot be considered sufficient to conclude that the system is a medical device. Users can not automatically expect the manufacturer to have taken patient risk and patient benefit into account when designing the system. Neither the risk management process nor the product post-market monitoring to minimize patient risk can be taken for granted. Other national legislation might however be applicable.

Software for diagnostic purposes

A common function of the standalone software programs in the health care system is to provide information that contributes to diagnosis and treatment. This is an important medical function that falls under the regulatory definition of a medical device.

Annex 9, paragraph 1.6, of directive 93/42/EEC on medical devices contains a specific definition applicable tor software for diagnosis:

> *Active device for diagnosis*
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> *Any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.*

Division into Modules

Many software solutions consist of combinations of various functions and components. It is usually this that is the whole idea of the software, i.e. to make complex combinations of and operations using clinical information and thus refine it into a valuable aid in the diagnosis and treatment of patients. The manufacturer combines software components such as data collection, processing, computing, communication and storage. In preparation for CE-marking, a software manufacturer may choose to define the product as a system that combines various features from different software components or keep to modules with more limited functionality. This affects the CE-marking in different ways.

A manufacturer who chooses a modular solution can screen out modules that have a general or purely administrative purpose and not include them in the CE-marking. It might, however, be necessary to demonstrate that the module in question has a sufficiently independent role in relation to the rest of the combination.

One risk associated with too far-reaching a division into modules is that the system's combined functionality and clinical benefit is lost, for example in the risk management process. Annex 1, paragraph 9.1, of directive 93/42/EEC on medical devices contains a requirement for compatibility with other modules:

> *If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use.*

Another risk connected with too far-reaching a division into modules is that it might lead to the exclusion of risk assessment of modules with apparently purely administrative functions but that may have a significant impact on combined functionality and safety.

If a manufacturer chooses the system solution, the system might include parts with a purely administrative function. If they constitute a minor part of the system, they need not burden the CE-marking process since they can be handled more easily in the risk management process.

How to handle standard software of uncertain origin

The software is also dependent on different components available in the market for general purposes such as operating systems, word processors, communications programs or browsers, so called SOUP (IEC term Software Of Unknown Provenance). These are not medical devices and their manufacturers can not be expected to have taken into account the medical aspects and patient safety. A manufacturer of a medical application must in the risk assessment consider the uncertainty in these general programs and allow for this in his risk assessment, according to annex 1, paragraph 9.1, of directive 93/42/EEC on medical devices, as cited above.

Reference to the CE-marking when procuring medical information systems

When procuring medical information systems, some care providers have requested that the systems should be CE-marked or that the manufacturer shall have a plan for doing so. This is an opening that has sometimes led to confusion and appeals.

An important issue is how the manufacturers in question have described the offered systems and how they match the caregiver's expressed needs. To avoid mismatch in responses, i.e. where the order and offer describe different or imprecise system characteristics, what the caregiver states in the specification is important. One must keep in mind whether the specification describes a medical device with a pronounced medical purpose, or whether it can be interpreted as if the buyer is prepared to accept a system where no patient perspective is taken into account by the manufacturer.

Hardware

The question of what hardware the software runs on is important but often overlooked. Hardware such as computers, servers, networks, nodes, switches, etc. are normally not medical devices. However, they have a large impact on the proper functioning of the software. Based on his risk management process, the manufacturer of the medical software is to predict and describe the requirements for suitable hardware environment and the need for regular safety measures.

The user then has to either abide by the manufacturer's recommendations or take personal responsibility for his or her own different solutions. The manufacturer can only take responsibility for what is covered by the risk management process.

Software via the Internet

Instead of installing it on their own servers or computers, a care provider may choose to use the software over networks, such as the Internet, from a server located on the manufacturer's premises. This is sometimes called "software as a service" and means that the owner of the server is responsible for operation and maintenance. Users 'only' use the product. From a regulatory perspective, such software, if it has a medical purpose, becomes subject to the medical device regulations and must be CE-marked, when it is made available to the user.

So-called "apps" shall also be CE-marked if they can be considered to have a medical purpose according to the definition of a medical device. A cell phone or "smartphone" that the software is run on, or through, however, is not a medical device unless it is converted for an explicit medical purpose. Otherwise, what is said above about hardware applies.

What is happening in the Swedish market in 2012?

One problem is that the question of what should be considered medical software is relatively new to the market. The European medical device directives were made clearer in 2007 through amending directive 2007/47/EC. The clarification is actually based on a new understanding and interpretation and was therefore not a new requirement. However, it has not been considered by either the manufacturers or the authorities in a satisfactory manner before.

As a reaction to this, the MPA, in consultation with various representatives of industry, healthcare and government agencies, have drawn up and published the document "Proposal for Guidelines regarding Classification of Software Based Information Systems used in Health Care"[2]. Today we have reached a good consensus in the market in Sweden and some other countries.

The guidelines developed by the European Commission in the form of a MEDDEV are in good agreement with the Swedish guide from 2009. The document designated MEDDEV 2.1 / 6 has a more limited purpose as it is only directed at manufacturers. It is in this context also important to note that the use of complex medical information systems differs significantly between the European Union's member states. There are therefore some sections, especially the examples, which need to be clarified so that they reflect and describe the systems currently on the market.

The MPA has therefore now launched a project to update the Swedish guide. A working group with representatives from the National Board of Health and Welfare, the Swedish Association of Local Authorities and Regions (Health, IT and MT operations), Swedish Medtech / Labtech, Intertek and the Swedish Standards Institute will participate in the project.

In summary:

Standalone software qualifies as a medical device if the manufacturer's stated purpose of the software meets the definition of a medical device

Among other things, the following requirements must then be met:

1. The product shall have adequate functions that support its intended use
2. Patient safety shall be considered in the risk assessment
3. The manufacturer shall demonstrate that the performance of the product really meets the medical purpose, for example by (clinical) evaluation
4. The product shall be CE-marked

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[2] http://www.lakemedelsverket.se/english/product/Medical-devices/

If the manufacturer has described a product as having a medical purpose, it shall be CE-marked. A user can then expect that the manufacturer has taken into account patient risk and patient benefit in designing the system. If a system is not described as a medical device, but only in technical / administrative terms, one can not automatically assume that the manufacturer has dealt with the patient safety aspects.

Safety comes first and in individual cases the availability of a product may be of more benefit to patients than a market suspension for formal reasons. In specific cases and if necessary, manufacturers may therefore be granted a limited period to make adjustments after submitting an appropriate and acceptable risk assessment.

This MPA information is not a decision in the legal sense but should be seen as the agency's present view based on available information. If, after this, any new information becomes available, the MPA's view may be changed.