Certain aspects on medical devices software law regulation

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ABSTRACT

Introduction: some kind of easiness of entry in creating software products on various computing platforms has led to such products being made available perhaps without due consideration of potential risks to users and patients and the most valuable reason for this have been lack of regulatory clarity. Some key points on legal regulation of abovementioned sphere is a base of this study.

Material and methods: Ukrainian legislation, European Union`s Guidelines on the qualification and classification of standalone software; Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices that works in United States of America. Article is based on dialectical, comparative, analytic, synthetic and comprehensive research methods.

Conclusion: in accordance with Ukrainian legislation, software that has a medical purpose could be a medical device. Ukrainian legislation which is established on European Union Medical Devices Directives divide all medical devices on classes. But there aren't any special recommendations or advices on classifications for software medical devices in Ukraine. It is necessary to develop and adopt guidelines on the qualification and classification of medical device software in Ukraine especially considering the harmonization of Ukrainian legislation with the EU legislation, develop special rules for the application of the national mark of conformity for medical device software and defined the «responsible organization» for the medical device software approval process.

KEY WORDS: medical purpose software, qualification and classification, responsible organization.

INTRODUCTION

One of the areas of significant growth in medical devices sphere has been the role of software – as an integral component of a medical device, as a standalone device and more recently as applications on mobile devices. Such growth requires appropriate law regulation to minimize law gaps and respective risks for large number of users of such software.

The low barriers to entry in creating software products on various computing platforms has led to such products being made available perhaps without due consideration of potential risks to users and patients.

Some of the reasons for this have been lack of regulatory clarity (it's not always clear what regulations apply, or if a software product itself qualifies as a medical device), and consequently little or confusing guidance from regulatory authorities has been provided, as well as a lack of standards to guide developers [1].

MATERIALS AND METHODS

Ukrainian legislation, European Union`s Guidelines on the qualification and classification of standalone software; Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices that works in United States of America. In article were used dialectical, comparative, analytic, synthetic and comprehensive research methods.

RESULTS END DISCUSSION

In accordance with Ukrainian legislation, software that has a medical purpose could be a medical device [2].

A medical device is defined as software intended by the manufacturer to be used for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiological process;
- control of conception.

In US, EU and other countries there are special documents which consist of guidelines on the qualification and classification of medical device software:

- EU - Guidelines on the qualification and classification of standalone software;
- US - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

It is very important to develop and adopt such guidelines in Ukraine especially considering the harmonization of Ukrainian legislation with the EU legislation. As an example, we can use EC`s Guidelines on the qualification and classification of standalone software.

Generally medical purpose software [1] consists of:

1. software in a medical device (sometimes referred to as "embedded" or "part of");
2. software as a medical device (along-standing software, apps).

If software is defined by manufactures as software with medical purpose it automatically falls under technical requirements that concerns medical devices.

Table I. Classifications for software medical devices

Rule	Software
Implementing Rule 2.3	Software, which drives a device or influences the use of a device automatically falls into the classification of that device.
Rule 9	Active therapeutic devices are generally Class IIa however they are Class IIb if potentially hazardous then Class IIb.
Rule 10	Active devices intended for diagnosis are generally Class IIa – however Class IIb if potentially hazardous
Rule 12	All other active devices are Class I.
Rule 14	All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class IIb.

Ukrainian legislation which is established on EU Medical Devices Directives divide all medical devices on classes. The classification rules are based on the vulnerability of the human body taking account of the potential risks associated with the technical design and manufacture of the devices.

There aren't any special recommendations or advices on classifications for software medical devices in Ukraine. That is why we propose to use EU practice in this sphere (Table I):

While compliance of Class I devices is based on self-declaration by the manufacturer, all other devices require use of a notified body to assess compliance [3].

It would be great to consolidate the same rules in a document, which would be mandatory for Ukrainian manufactures of medical devices software.

Individual medical devices must be marked by national conformity mark. Requirements for using national conformity mark is regaled by Cabinet of Ministers of Ukraine Decree «On approval of the form, describing the mark of conformity with technical regulations, rules and conditions for its application» [4].

In accordance with this document mark of conformity with technical regulations (hereinafter - a sign of conformity) applied to its products or to sign the technical data so that it was visible, legible and indelible.

In the case where it is impossible or unreasonable due to the nature of products, conformity mark applied to the packaging and to the accompanying documents if the documents provided relevant technical regulations [4]. Feature considering software as a product to fulfill these requirements is not possible. That is why this question must be additionally developed and regulated.

As well general medical devices have to provide instructions for use (IFU). In practice these instructions are provided with medical device in paper form. Once again it can be difficult to realize for along-standing medical device software which can be sale via internet.

Medicines & Healthcare products Regulatory Agency recommends the following in this regard:

You don't need to provide instructions for Class I and IIa devices if they can be used safely without them. You can provide electronic instructions if they are needed and the device is intended for professional users and the electronic instructions for use of medical devices regulations apply. Otherwise, the paper IFU shall be provided with the device.

The IFU should contain all the information needed to verify whether the device is properly installed and can operate correctly and safely [3].

We believe these recommendations are reasonable and those that can and must be applied in Ukraine to avoid abovementioned risks.

Leaves open the topic of the «responsible organization». Another words, who will take responsibility for the medical device software approval process, including classification of the software medical devices, prepare declaration, notify body to assess compliance, mark by national conformity mark etc. As we know software is usually developed by developers who are private entrepreneurs with all the features arising.

Each of them can create "ready for use" software or only part of software code, which is unusable by itself without combining with other parts. After that intellectual property rights on this code can be transfer to the client. Client, in turn, can combine parts of obtained software or sell it to another company party. This can be repeated several times with no restriction. So, who is the «responsible organization»?

We think that it has be natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of *making the medical device available for use*, *under his name*; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person (s). The key point in these definitions are: medical device available for use (not a part of software) and this device will be distributing under the natural or legal person`s name.

CONCLUSION

Medical devices software is a product with some level of risk for its users. That is why the scope of its manufacturing and distributing must be regulated by government. The first steps in this direction should be:

1. Developing and adopting the guidelines on the qualification and classification of medical devices software.
2. Developing special rules for the application of the national mark of conformity for medical device software.

3. Resolve the issue of the instructions of use for medical device software.
4. Defined the «responsible organization» for the medical device software approval process.

Accomplishing them the risks of negative effect of such products will be minimized to admissible level, thus achieving the goals, arising from Ukraine-EU law harmonization.

REFERENCES

1. Brian Goemans. Medical device software standards. 5 November 2015. See http://www.emergogroup.com/resources/articles/white-paper-medical-device-software-standards
2. See http://zakon3.rada.gov.ua/laws/show/753-2013-%D0%BF6 Paragrafh 9 of General part.
3. See https://www.gov.uk/government/publications/medical-devices-software-applications-apps/medical-device-stand-alone-software-including-apps
4. See at http://zakon5.rada.gov.ua/laws/show/1184-2015-%D0%BF

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