EU: How Medical Software are currently regulated?

Towards a Global Vision on Medical Software

AHWP – Technical Committee DITTA Workshop

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Definition of medical device (MD)

Article 1 of Directive 93/42/EEC

'**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:

— 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, 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;

EU Commission Regulation Proposal on IVD: Software

Art. 2(2)

'in vitro diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, software NEW or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information

What is a stand alone software?

Guidance document MEDDEV 2.1/6

(January 2012)

Stand alone software means

"software which is not incorporated in a medical device at the time of its placing on the market or its making available"

How to qualify a stand alone software as a medical device?

- The European Commission created in December 2009 a Working Group to better define what type of software should be subject to the medical device regulations and which requirements should apply.

- This Working group issued in January 2012 a Guidance document for the qualification and classification of stand alone software used in healthcare: **MEDDEV 2.1/6**

- This Guidance document is giving a list of concrete examples of stand alone softwares to help in the qualification and classification.

- What next? Update of the Guidance needed to include mobile phone Apps and other innovative products

When stand alone software is not a MD?

Recital 6 of Directive 2007/47/EC:

"… software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is a medical device.

"Stand alone software for general purposes when used in a healthcare setting is not a medical device."

When stand alone software is a MD?

Stand alone software is a MD when:

Satisfies the definition of a MD

therefore

Has a medical purpose

[Directly control an apparatus (e.g. radiotherapy treatment), provide immediate decision triggering information (e.g. blood glucose meters), or can provide support for healthcare professionals (e.g. ECG interpretation)]

Stand alone software as an accessory of a MD or an IVD

Stand alone software that does not meet the definition of a medical device or of an IVD medical device but is intended by the manufacturer to be an ***accessory to a medical device, or an IVD medical device****, falls respectively under the scope of Directive 93/42/EEC or Directive 98/79/EC.*

Stand alone software: active MD

When it meests the definition of MD, Stand alone software shall be considered as an

active medical device:

"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"

What is happening in some EU Member States?

1. In Sweden

- Medical Product Agency is updating its national guidance document on medical software to reflect the international developments including the European MEDDEV.

2. In France

- Draft decree on the mandatory certification of software to facilitate the issuing and dispensing of medical prescriptions.

3. In the UK

- Department of Health is calling on software developers to create apps for use by the NHS.

Thank you for your attention!

European Commission

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http://ec.europa.eu/health/medical-devices/index_en.htm