Software within the medical device regulatory framework in the EU

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Erik Hansson, Deputy Head of Unit, DG GROWTH - Health Technology and Cosmetics, European Commission
Outline – software within the medical device regulatory framework in the EU

1. Legal background
2. Revision of the Medical Devices legislation
1. Legal background

Safety and performance requirements for software falling under the definition of a medical device (MDs) or an in-vitro diagnostic medical device (IVDs) are regulated by the respective directives:

- Directive 93/42/EEC (MDs)
- Directive 98/79/EC (IVDs)
Some important points to know

- A medical device is intended to have a **medical purpose** with an action other than pharmacological, immunological or metabolic.

- Software that are **part** of medical devices must fulfil the requirements of the medical devices legislation. Also if no medical purpose but essential to maintain function of medical device (**accessory**).

- The Manual on Borderline and Classification clarifies that in the medical device regulatory context, **apps are regulated as software**.
What happens if a software/app is a medical device?

- It must comply with the safety and performance requirements set in Annex I to the Directives.
- Such compliance must be assessed through a specific conformity assessment procedure, which is proportional to the risk-class of devices:
  - For low-risk products (Class I), the manufacturer can provide.
  - For all other products (Classes IIa, IIb and III), a control must be done by a Notified Body.
- Other requirements for manufacturers regard registration, post-market surveillance, incident reporting.
Examples

Class I software
a) orthopaedic planning software to measure interpedicular distance or sagittal diameter of the spinal canal.

Class IIa software:
a) Software for the presentation of the heart rate or other physiological parameters during routine checkups

Class IIb software:
a) radiotherapy planning system used to calculate the dose of ionizing radiation to be administered to the patient, insulin dosage planning standalone software.
b) Software for the presentation of the heart rate or other physiological parameters for intensive care monitoring
Borderline and classification issues

A- "Guidelines on the qualification and classification of standalone software used in healthcare within the regulatory framework of medical devices" (MEDDEV 2.1/6, January 2012)

- provides practical advice to determine when a software/app falls under the definition of a medical device or of an IVD medical device as well as its class.
- update will be published in the summer.

B- Manual on Borderline and Classification

- provides a list of concrete qualification/classification examples for which consensus was achieved among Competent Authorities.
International angle

- In the meantime, the EU has been involved in the ongoing work of the IMDRF Software as a Medical Device Working Group for SaMD clinical evaluation.

- The Group has already produced guidance on key definitions, risk categorization principles and applicability of QMS principles to software.

- EU mirror group for regulators to the IMDRF WG has been created in December 2015 due to growing interest of the EU Member States.
How to transpose IMDRF work at the EU level

A- *IMDRF Guidance on key definitions*:
   - The new EU MEDDEV will include the definition of SaMD
   - Deletion of the word standalone from the definition of software is currently under discussion in MDR negotiations

B- *Guidance on risk categorisation*:
   - Some of the principles might be used for laying dedicated rules on software in the new EU Regulations

C- *Guidance on applicability of QMS*:
   - This guidance is more intended to inform the standardisation work, for which the Commission is not directly responsible
2. New proposals for Regulations on MDs and IVDs

- New Regulations on MDs and IVDs to replace the existing Directives.
- A political agreement on the two texts was reached at the tenth trilogue on 25 May
- Formal adoption is expected by the end of the year
- Some of the main issues discussed during the negotiations which are related to medical software:
General safety and performance requirements under discussion

- repeatability, reliability and performance according to the intended use
- the principles of development life cycle, risk management, verification and validation
- the use of software in combination with mobile computing platforms
- IT security measures, including protection against unauthorised access
Location of the software

✓ Possible deletion of the word "standalone" in the text of the new Regulation
✓ With this amendment, medical software would be qualified and classified regardless of its location
Regulation of software without a medical purpose

- Scope of the new Regulations possibly including medical devices with both direct and indirect medical purpose (EP first reading amendment)

- With this amendment, lifestyle and wellbeing apps would be covered under the new Regulations

- Commission and Council opposed to this amendment
Classification rules for software as a medical device

- Possibility to provide dedicated rules on software
- Consideration of risk categorisation principles established in IMDRF
- Possible mandatory clinical investigation procedures for certain medical software
Useful links

- MEDDEV Guidance 2.1/6

- Manual on Borderline and Classification
Thank you for your attention!