Software as a Medical Device: Regulatory Gaps and Uncertainties?

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Overview

1. Key aspects of medical devices regulatory framework & software as a medical device (SaMD)
2. Gaps and uncertainties in the context of DIY APS:
    I. Who/what organisation counts as a ‘manufacturer’
    II. What it means to place ad medical device on the market
    III. Whether the ‘form’ of software makes a difference
3. Intangible nature of software makes it a bad regulatory ‘fit’ with regulations constructed for physical goods

The Law & Software as a Medical Device I

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- (Medicines & Medical Devices Act 2021)
- The Medical Device Regulations 2002 implements:
  - EU Directive 93/42 on general medical devices
  - EU Directive 90/385 on active implantable medical devices
  - EU Directive 98/79 on in vitro diagnostic medical devices
- Medical Devices (Amendment etc) (EU Exit Regulations 2019 - continued operation of 2002 Regulations
- Medical Devices (Amendment etc)(EU Exit) Regulations 2020 - dual system of regulation for markets in Northern Ireland and Great Britain
- EU Medical Device Regulations 2017/745 (EU MDR) and EU In Vitro Diagnostic Regulations 2017/756 (EU IVDR) - apply in Northern Ireland only

The Law & Software as a Medical Device II

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What is a Medical Device?

By Reg 2(1) 2002 regulations [as amended by Reg 2(h) Medical Devices (Amendment) Regulations 2008] a "medical device" is:

"any instrument, apparatus, appliance, *software*, material or other article… *intended by the manufacturer*" to have one (or more) of the listed medical purposes including "diagnosis, prevention, monitoring, treatment or alleviation of disease".

Key Issues

- "Software" added retrospectively in 2008 without changing other aspects of the Regulation.
- In general, EU and UK law treats software as a "service" not as "goods" or "products".

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Who is the Manufacturer?

A “manufacturer” according to the 2002 Regulations is either:

“the person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name…”

Or

“any other person who assembles, packages, processes, fully refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name…”

Definition in EU Directives and MDR provides that the “manufacturer” will be “a natural or legal person” who also “markets the device under its own name or trademark”.

Key Points

- Presupposes tangible physical object
- Presupposes easily identifiable central company or natural person responsible for manufacture

Explaining DIY APS

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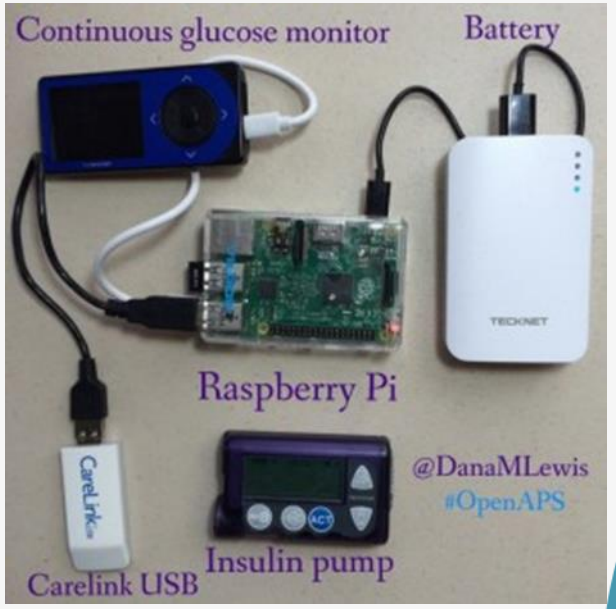
- Open source software (OSS) developed outside context of commercial company
- Software installed on either a small computer (e.g. Raspberry Pi) or a smart phone allows a persons continuous glucose monitor and insulin pump to talk to each other
- Automatically adjusted insulin delivery in real-time



What does it mean to “place on the market”? I

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To “place on the market” is defined in 2002 Regulations as:

> “the first making available in return for payment or free of charge of a new or fully refurbished device… with a view to distribution, use, or both, on the… market”.

A definition of “making available on the market” was provided by of Regulation (EC) No 765/2008 for Accreditation and Market Surveillance which provided that “making available” a “product” was done in the course of a “commercial activity” albeit one that need not involve exchange of money.

What does it mean to “place on the market”? II

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Three questions arising from this :

1. At what point, or by what act(s), is an SaMD said to be placed on the market?
2. How can it be determined that they are intended to be placed on the market in the UK?
3. What constitutes a “commercial activity” for these purposes?

What does it mean to “place on the market”? III

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At what point/when can SaMD be said to be placed on UK/EU market?

- Software can be downloaded from anywhere in the world to anywhere in the world – so at what point is it placed on the (UK) market?
- Where software/code hosted on servers outwith geographical jurisdiction (outside UK/EU) then they are not covered by the Regulations
- MHRA position seems to be the DIY APS software will not be covered by the Regulations
- Unsatisfactory in digital age

What constitutes a commercial activity?

- Need not involve exchange of money
- Little other guidance for projects like DIY APS which are branded, organised and engage in outreach but are not-for-profit

Does form matter? I

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- Unclear if there is a legal distinction between pre-compiled software and uncompiled software - typified by DIY APS
- MHRA and EU simply define software as “a set of instructions that processes input data and creates output data”.
- General EU guidance – in most legislation “goods” refers to “finished” products – may be difficult to determine when this has occurred for SaMD
- Defence in General Product Liability Directive if it can be shown that the product has not be placed on the market, by someone other than the manufacturer with their knowledge
- MHRA guidance suggests uncompiled software is included within ambit of the regulations which could extend to DIY APS

Does form matter? II

Muddying the waters of the “form” question is the further issue of how software is supplied…

- In UK/EU law there is a general distinction between software/digital products supply via tangible medium (CD, DVD etc) or via digital download:
  - Software on a tangible = “good”
  - Digital downloads = service
- Tangible/intangible divide stems from St Albans City and District Council v International Computers Ltd 1996 from obiter comments by Sir Iain Glidewell
- Recent cases:
  - *UsedSoft GmbH v Oracle International Corp* (Case C-128/11) - “sale of goods” for purposes of principle of exhaustion
  - The Software Incubator Ltd v Computer Associates Ltd - Opinion of the AG December 2020 software constitutes “goods” for purposes of Commercial Agents Directive

Does form matter? III

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CJEU: C-410/19 Software Incubator v Computer Associates:

- Art.1(2) Commercial Agents Directive (86/653) includes supply of software in return for payment where accompanied by grant of perpetual licence to use software.
- Approach of Attorney General broadly followed.
- Concepts of “goods” and “sale of goods” to be interpreted in the context of the legislation and circumstances in which they are applied.
- Definition of “goods” makes no reference to or distinction between tangible and intangible artefacts
- Supplying software electronically had same economic effect as transfer via tangible medium such as CD.

Key Point:

- EU cases may be instructive but inconsistent treatment in case law underlines ambiguity in the Medical Device Regulations.

Concluding Thoughts: Time to Plug the Gaps?

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- SaMDs sit uneasily within framework for medical device regulations designed with physical goods at its core
- Leads to interpretative and operational gaps and ambiguities relating to:
  - Identifying a manufacturer
  - Determining what it means to “place on the market” in the context of software
  - Determining whether or not form matters
- Compounded by lack of case law for guidance

Thank you

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Work on this presentation was generously supported by a Wellcome Trust Investigator Award in Humanities and Social Sciences 2019-2024 (Grant No: 212507/Z/18/Z).