Software as a Medical Device
Living in a Material World?

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Overview

1. Key aspects of medical devices regulatory framework & software as a medical device (SaMD)
2. Gaps and uncertainties SaMDs (especially open source):
    I. Who/what organisation counts as a ‘manufacturer’
    II. Intended use
    III. What it means to ‘place on the market’/’put into service’
    IV. Final finished product
    V. 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

Regulating SaMDs in the UK: Complex & Messy

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- (Medicines & Medical Devices Act 2021)
- Medical Device Regulations 2002 (as amended)
- In Great Britain 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
- In Northern Ireland implements:
    - EU Medical Device Regulations 2017/745 (EU MDR)
    - EU In Vitro Diagnostic Regulations 2017/756 (EU IVDR)

[Medical Devices (Amendment etc) (EU Exit) Regulations 2019, Medical Devices (Amendment etc)(EU Exit) Regulations 2020, & Medical Devices (Northern Ireland Protocol) Regulations 2021]

Application & Interpretation of Regulations

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Four key interrelated requirements (at least):

1. A device within the meaning of the definition given of ‘medical device’;
2. Device is *intended* by the manufacturer to have one (or more) of a particular set of listed *purposes* or *uses*
3. Existence and identification of a person or body within the definition of ‘manufacturer’; and
4. Whether a device is, or is intended to be, ‘placed on the market’ or ‘put into service’.

What is a Medical Device?

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- 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”.

- Wider list of medical purposes in EU MDR/IVDR

- Regardless, software is explicitly captured by the Regulations

Intended Purpose/Use….

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- Reg 2(1) “intended purpose” means—

  (a) in relation to an active implantable medical device, the use for which it is intended and for which it is suited according to the data supplied by the *manufacturer* in the instructions relating to it;

  (b) in relation to any other medical device, the use to which the device is intended according to the data supplied by the *manufacturer* on the labelling, the instructions for use and/or the promotional materials

- MDR/IVDR → intention can be imputed from a range of source (e.g. packaging, instructions, marketing, other statements), not just explicit statements of manufacturers (Art 2(12)).

- EU Blue Guide

  “‘Use’ refers to the intended purpose of the product as defined by the *manufacturer* under conditions which can be reasonably foreseen. Usually, this is the end use of the product.”

Who is the Manufacturer? I

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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

Open Source Automated Insulin Delivery Systems

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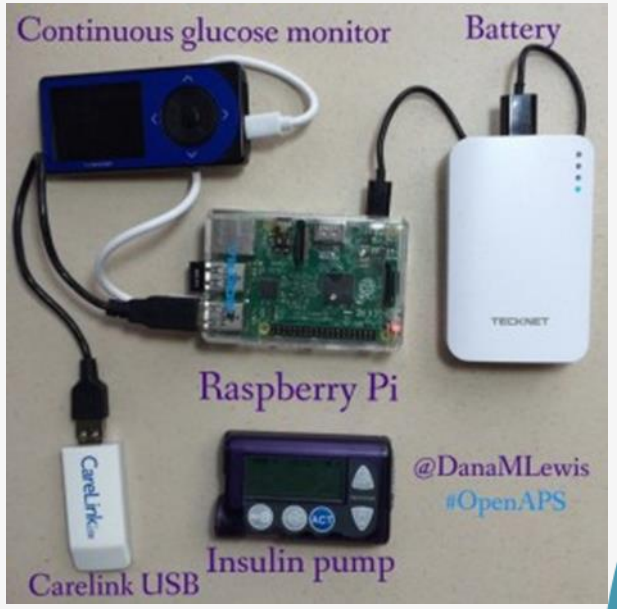
- Open source software (OSS) developed outside context of commercial company
- Software installed on either a small computer (e.g. Raspberry Pi/Edison board) or a smart phone allows a persons continuous glucose monitor and insulin pump to talk to each other
- Automatically adjusted insulin delivery in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



Who is the Manufacturer? II

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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”.

Does the end-user become the manufacturer?

‘Place on the market’ or ‘put into service’? 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”.

To “put into service” means:

(a) … the making available of the device to a registered medical practitioner for implantation;
(b) … the first making available of the device in the Community to a final user, including where a device is used in a professional context for the purposes of medical analysis without being marketed

‘Place on the market’ or ‘put into service’? 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 or put into service?
2. How can it be determined that they are intended to be placed on the market/put into service in the UK?
3. What constitutes a “commercial activity” for these purposes?

‘Place on the market’ or ‘put into service’? 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), what is their status?
- Does falling outwith geographical boundaries renders them also outside of jurisdictional boundaries?
- Unsatisfactory in digital age

What constitutes a commercial activity?

- Need not involve exchange of money
- Little other guidance for projects like OS AID projects which are branded, organised and engage in outreach.
- Are not-for-profit, but have surely gone beyond being ‘hobbyists’

Final Finished Product?

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- Pre-compiled software vs uncompiled software
- 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 SaMDs
- However, MHRA guidance suggests uncompiled software is included within ambit of the Medical Devices Regulations
- Defence in EU Product Liability Directive and UK Consumer Protection Act if it can be shown that the ‘product’ has been placed on the market by someone *other than* the manufacturer *without* their knowledge

But….

- In their current incarnation these relate to ‘products’ qua physical goods not software….

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Does Form Matter?

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? II

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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: Living in a Material World

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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:
    1. Intended use
    2. Identifying a manufacturer or legal responsible person;
    3. Determining what it means to ‘place on the market’ or ‘put into service’when it comes to software;
    4. What final finished product means in the context of certain SaMDs; and
    5. Determining whether or not form matters

- Compounded by lack of case law for guidance
- Need to find ways to make software more ‘material’ for the law.

Thank you

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