The new Medical Devices Regulation and the potential impact on services

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Prior to my retirement from the NHS in 2009 I was head of Clinical Engineering in the Cardiff and Vale Trust.

I had been involved in formal safety Standards for medical devices at an international and UK level and wanted to continue that work.

From 2011 to 2018 I chaired the international standards committee IEC SC 62A responsible for the Standards on medical electrical equipment.

From 2012 to date I have been involved on behalf of the Institute of Physics and Engineering in Medicine (IPEM) in lobbying on aspects of then draft Medical Devices Regulation.

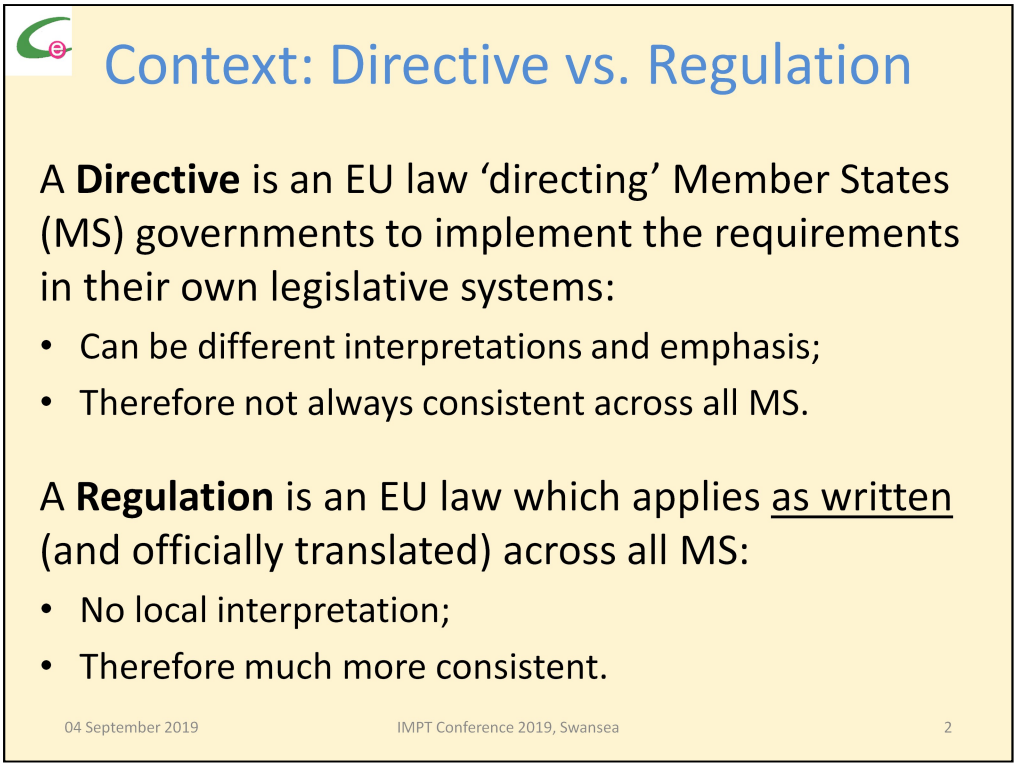
I went to Brussels twice to talk to MEPs particularly on the issue of in-house development and use of devices which the Commission, in their original first draft, wanted to make subject to full conformity assessment. I also became and continue to be involved with the MHRA's stakeholder group on the whole impact of the new Regulations.

I contributed to a briefing paper put out by the NHS Confederation European Office on the impact of the new Regulations on in-house manufacture.

https://www.nhsconfed.org/-/media/Confederation/Files/public-access/European-Office/EU-briefing-24-Medical-devices_2018_Final.pdf?la=en&hash=795CCABA01EAAE1F463D7F0474331E01E50A89FE

In November 2018 I was asked to do a review of the Maxillofacial and Rehabilitation Engineering Departments at Morriston Hospital in Swansea, in respect of their need to establish formal quality management systems.

More recently I have been asked by Welsh Government to help coordinate the work needed to bring all relevant departments into line with the new in-house manufacture and use requirements.



What is the difference between EU directives and regulations?

"Directives are addressed to member states rather than their citizens, and are therefore only legally binding upon the states themselves.

Under the process known as "transposition" the directive sets the framework but the practical details of implementation are left for the member states to decide.

By contrast, regulations have "general application". That means they are binding on individuals and effectively form part of domestic law as soon as they are made. It is generally only necessary to amend existing national provisions that are inconsistent with regulations, rather than make new legislation altogether."

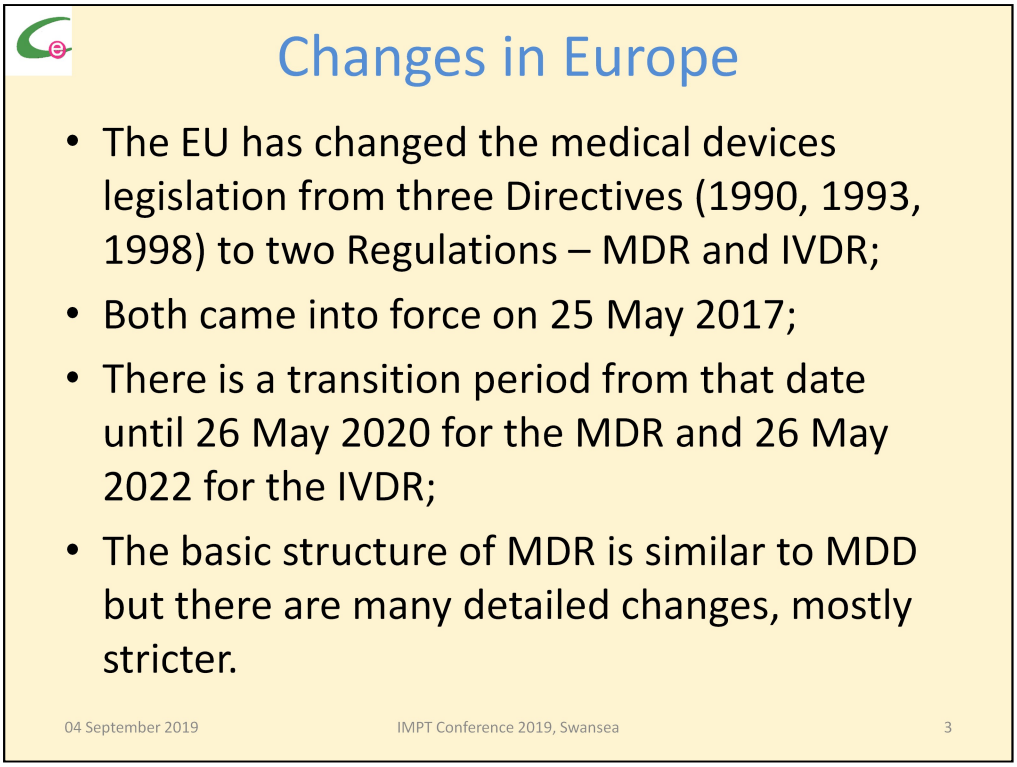
Timothy Jones, a lawyer at the UK Treasury Solicitor's Department
www.bbc.co.uk/2/hi/europe/8160808.stm

Also see
http://www.towers.fr/essays/difference_between_a_directive_and_a_regulation.pdf/
world/europe/8160808.stm

"According to Article 189 of the Treaty of Rome a directive allows Member States of the EU the chance to adjust the legal text to align with national requirements or to ensure that it fits the national legislation of that state.

A regulation on the other hand is binding in its entirety and each Member State has to accept the same definition. A regulation does not allow countries the opportunity to interpret the ruling in different ways."

Nevison G. http://www.electronicsweekly.com/blogs/electronics-legislation/2011/05/difference-between-a-directive.html



The first draft of the proposed Regulation was issued in late 2012.

There has been very considerable negotiation since then but the new Medical Devices Regulation (MDR) and the In-vitro Diagnostic Devices Regulation (IVDR) are both now in force.

There will be a three year transition period for most aspects of the MDR until 'full application' on 26 May 2020. For the IVDR the transition period is five years until 26 May 2022.

During the relevant period, for most aspects, either the previous Directive or the new Regulation can be used.

Access to the texts

The MDR:

http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2017:117:TOC

The MDD:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:en:PDF

Aims

Medical Devices Directive/Regulation

The aims of both are two-fold; in the words of the new Regulation they are "inseparably linked"

1. To ensure the smooth functioning of the internal market (e.g. eliminating technical barriers to trade within EU);
2. Ensuring a high standard of safety of any medical devices placed on the market or put into service within the EU.

The Regulations contain (among much more):

- general safety and performance requirements (GSPR) for devices, detailed in Annex1
- requirements for risk classification of devices
- requirements for assessing the conformity of devices to the GSPR
- requirements on manufacturers to register as such
- requirements on manufacturers to uniquely identify device
- requirements to provide a card for patients who have had a device implanted
- specific requirements for custom made devices

General Safety and Performance Requirements (GSPR)

- Called the Essential Requirements in the MDD
- Set out in Annex I
- Meeting these is the legal requirement
- Harmonised Standards may give a 'presumption of conformity' to relevant GSPR

ANNEX I GENERAL SAFETY AND PERFORMANCE REQUIREMENTS *[part of page 1 of 24 pages]*

CHAPTER I GENERAL REQUIREMENTS

1. Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.
2. The requirement in this Annex to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio.
3. Manufacturers shall establish, implement, document and maintain a risk management system. Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating. ….
4. Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, Manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, manufacturers shall, in the following order of priority:
    a) eliminate or reduce risks as far as possible through safe design and manufacture;
    b) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and
    c) provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users.

Manufacturers shall inform users of any residual risks.

…

Article 10.9

9. … Manufacturers of devices, other than investigational devices, shall establish, document, implement, maintain, keep up to date and continually improve a quality management system that shall ensure compliance with this Regulation in the most effective manner and in a manner that is proportionate to the risk class and the type of device.

The quality management system shall cover all parts and elements of a manufacturer's organisation dealing with the quality of processes, procedures and devices. It shall govern the structure, responsibilities, procedures, processes and management resources required to implement the principles and actions necessary to achieve compliance with the provisions of this Regulation.

The quality management system shall address at least the following aspects:

(a) a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for management of modifications to the devices covered by the system;

(b) identification of applicable general safety and performance requirements and exploration of options to address those requirements;

(c) responsibility of the management;

(d) resource management, including selection and control of suppliers and sub-contractors;

(e) risk management as set out in in Section 3 of Annex I;

(f) clinical evaluation in accordance with Article 61 and Annex XIV, including PMCF;

(g) product realisation, including planning, design, development, production and service provision;

(h) verification of the UDI assignments made in accordance with Article 27(3) to all relevant devices and ensuring consistency and validity of information provided in accordance with Article 29;

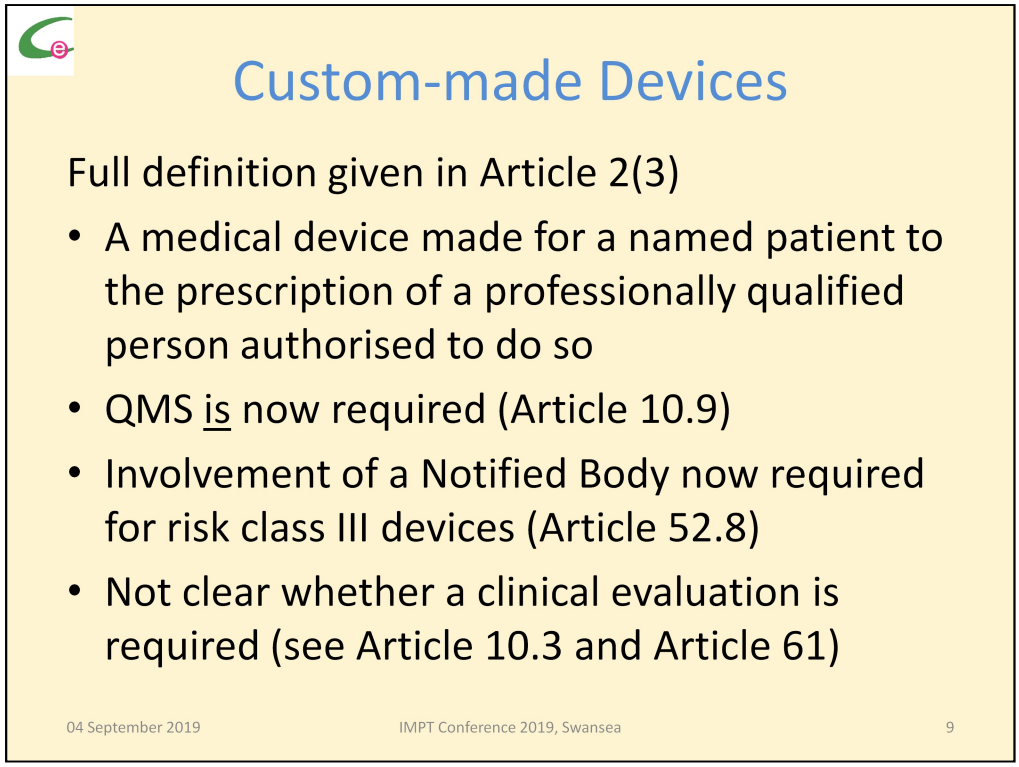
(i) setting-up, implementation and maintenance of a post-market surveillance system, in accordance with Article 83;

(j) handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders;

(k) processes for reporting of serious incidents and field safety corrective actions in the context of vigilance;

(l) management of corrective and preventive actions and verification of their effectiveness;

(m) processes for monitoring and measurement of output, data analysis and product improvement



Article 2

(3) 'custom-made device' means any device specifically made in accordance with a written prescription of any person authorised by national law by virtue of that person's professional qualifications which gives, under that person's responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs.

In-house manufacture and use

The Directives were silent on the issue of the status of devices made and used within the same health institution;
Therefore, the UK regulations made under the MDD did not apply to this activity.

The new Regulations specifically say that this activity is 'putting into service' – Article 5.4;
Therefore the MD and IVD Regulations apply;
However an exemption is allowed provided that certain conditions are met – Article 5.5.

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The UK interpretation was that devices put into service within the same legal entity which manufactured them did not meet the definition in the Directive of '*putting into service*'.

Therefore such activity was not covered by the Directive.

The European Commission and some other member states did not agree with this interpretation but this is a Directive …

There has been some pretty minimal guidance from MHRA on in-house developments under the MDD.

https://www.gov.uk/government/publications/in-house-manufacture-of-medical-devices

Essentially, if devices were/are made and used only within the same legal entity health institution, then the 2002 UK regulations giving force to the MDD do not apply.

General H&S law and civil law of negligence would apply.

Health Institution Exemption(HIE): Article 5

5.4 Devices that are manufactured and used within health institutions shall be considered as having been put into service.

5.5 With the exception of the relevant *General Safety and Performance Requirements* set out in Annex I, the requirements of this Regulation shall not apply to devices, manufactured and used only within health institutions established in the Union, provided that all of the following conditions are met:

(a) …

(h) … [my emphasis]

So the General Safety and Performance Requirements DO apply.

You have to document that you have considered all, show you meet all relevant ones and document reasons for those not met.

Provided that …

a) Devices are not transferred to another legal entity;
b) Manufacture and use occur under appropriate QMSs;*
c) Justify not using an available CE marked device;*
d) Info is provided on request to CA; MHRA in UK;
e) Make publically available a declaration of IHMU;
f) Design and risk management is documented in Technical File;*
g) All development is in accordance with the tech file;
h) Review experience and correct if necessary.*

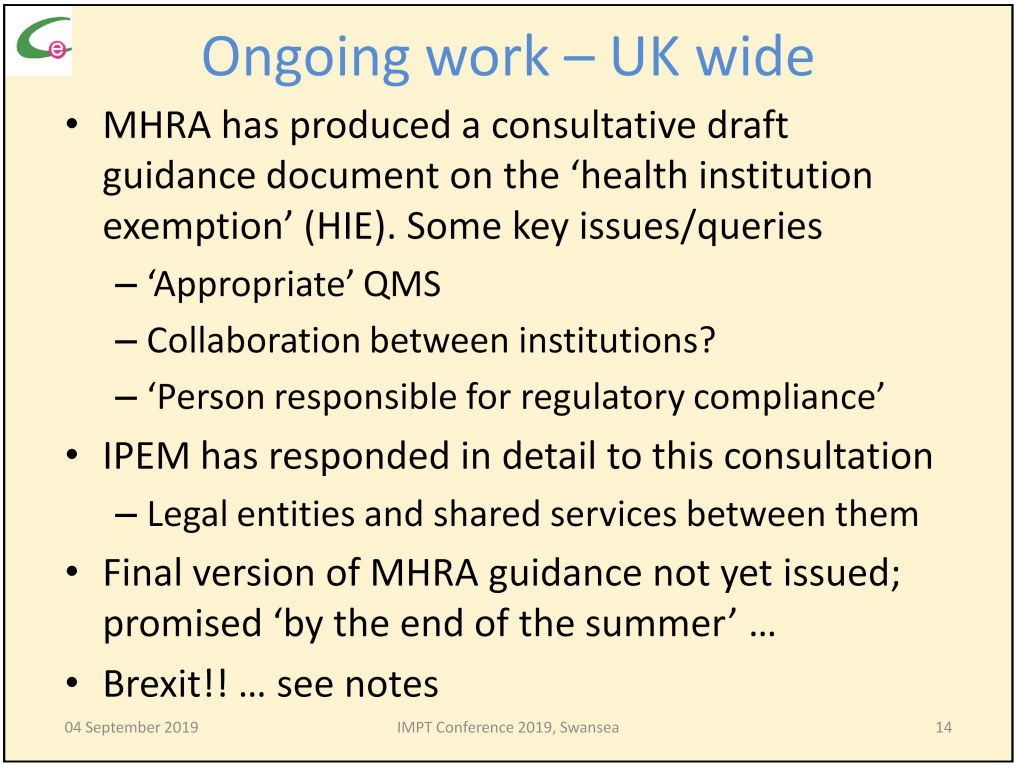
* requirements applicable for a research device

* These requirements would be the ones applicable for a research device

HIE vs. MDR custom-made rules

- HIE only available for devices used within the same legal entity
- Two scenarios:
  - Patient referred to your HI; prescription comes from within: IMO, HIE can be applied
  - Prescription comes from another HI, you make it and send it back; IMO, you are placing the device on the market. You must follow the MDR custom-made rules
- Can chose to apply MDR rules for everything

MDR requirement	Health institution exemption	Custom-made medical device
Comply with relevant GSPR	Yes	Yes
Applies to medical devices put into service	Yes	Yes
Applies to medical devices placed on the market	No	Yes
Written prescription	Not required	Required, by an authorised prescriber
Justification	Required	Not required
Scale	Not on an industrial scale	Not mass produced
Patient	Patient group or individual patient	Individual patient
Exemptions	General exemption with specific requirements	Specific exemptions apply
Person Responsible for Regulatory Compliance	Not required	Required
Quality System	Needs to be appropriate	As set out in Article 10.9
Demonstrate compliance	Publicly available declaration	Statement
Documentation	Required	Annex XIII requirements
Information available to MHRA	On request	On request
Registration with MHRA	Not required	Not required
Notified Body	None	Class III only
Post market	Review experience	Vigilance reporting requirements
Periodic Safety Update Report	Not required	Required



MHRA draft guidance document

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/675419/Health_institution_exemption_draft_for_public_consultation.pdf

Institute of Physics and Engineering in Medicine (IPEM) sent in a detailed and comprehensive response to this consultation, largely authored by Gerard Dean (a colleague from Nottingham) and myself.

Available at

https://www.ipem.ac.uk/Portals/0/HIE%20consultation%20-%20IPEM%20response.pdf?ver=2019-04-03-092153-370

Our comments raised strongly the issue of relationships between legal entities (individual Trusts or LHBs) and shared services between them e.g. NWIS providing services to all NHS Wales entities, each of which is a different legal entity or Clinical Collaboration Hubs in NHS England.

Regarding Brexit …

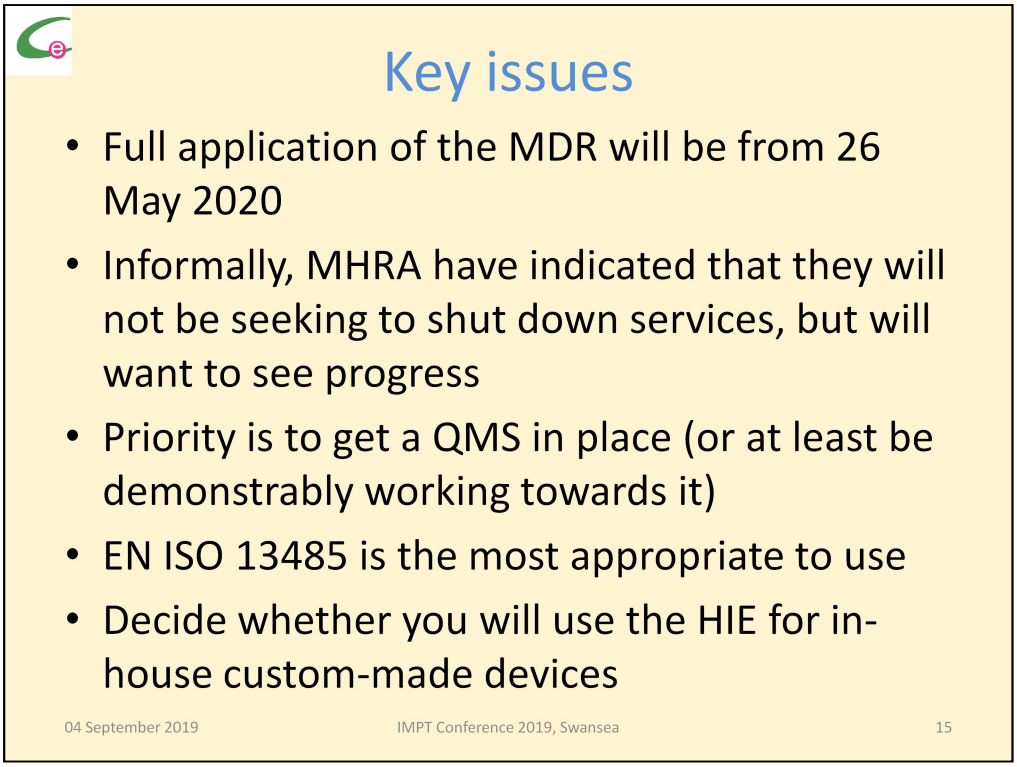
UK government have drafted and (I believe) had approved by Parliament an amendment to the 2002 UK Regulations which gave force to the MDD.

The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (as amended)

This takes the new MRD words, amends them to be UK specific e.g. removes references to the 'Union' and the 'Commission' but leaves all the detailed requirements unchanged including Article 5. The same for the IVDR.

In the event of a 'no-deal crash-out' these UK Regulations will come into force on 'exit day'. In the event of an agreed exit with a transition period, the EU Regulations will continue in force during that time. In the event of the UK remaining in the EU, clearly the EU Regulations will continue in force.

MHRA have made it clear that in any event they have no intention of diverging from EU Regulations.



EN ISO 13485:2016

Medical devices. Quality management systems. Requirements for regulatory purposes.

PD CEN/TR 17223:2018

Guidance on the relationship between EN ISO 13485:2016 (Medical devices. Quality management systems. Requirements for regulatory purposes) and European Medical Devices Regulation and In Vitro Diagnostic Medical Devices Regulation

Further information

- What is a medical device?
  - Note that software can be a medical device
- What constitutes in-house 'manufacture'?
  - Note that the exemption is for in-house manufacture AND use (IHMU)
- What does Article 5.5 say?
  - You must take account of the GSPR in Annex I
  - Note the requirement for a quality management system

See the three pages at the end of your papers

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The definition of an MD is detailed and specific and includes the phrase … *intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:* …

Note that an 'accessory for a medical device' as defined in Article 2.2, is regulated as if it is a medical device in its own right.

Devices made specifically for a research purpose do not meet the definition of a MD.

However, if the research is in pursuit of developing a new device and there is commercial intent then other parts of the MD Regulation come in to play.

If an in house developed device is later 'placed on the market' then the full conformity assessment and CE marking parts of the Regulation become applicable.

In my opinion, apart from some requirements to report on and make public in-house manufacture and use activity, the new Article 5.5 requirements are no more than **ought to** have been done as **best practice** under the previous arrangements.

REGULATIONS

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 5 April 2017
on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

(1) 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,

— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,

— providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

— devices for the control or support of conception;

— products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

(2) 'accessory for a medical device' means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s);

Adapted from MHRA draft guidance on the health institution exemption

In-house manufacturing

Manufacturing or modifying a device by a health institution could include:

- the putting together of a medical device from raw materials or component parts, or
- the complete rebuilding of an existing medical device, or
- making a new medical device from used devices, or
- fully refurbishing a medical device, or
- developing software that meets the definition of a medical device, or
- using a product for a medical purpose that is not CE marked as a medical device, or
- putting together combinations of medical devices and other equipment, or
- significant deviations from the instructions for use that alter the function, performance or purpose of a medical device, or
- using an existing medical device for a different purpose from that intended by the manufacturer, or
- modifying a medical device for a new purpose, function or performance;

and where this action is not explicit in a manufacturer's intended purpose or instructions for use.

If such activity is undertaken, then Article 5.5 must be applied.

CHAPTER II

MAKING AVAILABLE ON THE MARKET AND PUTTING INTO SERVICE OF DEVICES, OBLIGATIONS OF ECONOMIC OPERATORS, REPROCESSING, CE MARKING, FREE MOVEMENT

Article 5

Placing on the market and putting into service

1. A device may be placed on the market or put into service only if it complies with this Regulation when duly supplied and properly installed, maintained and used in accordance with its intended purpose.

2. A device shall meet the general safety and performance requirements set out in Annex I which apply to it, taking into account its intended purpose.

3. Demonstration of conformity with the general safety and performance requirements shall include a clinical evaluation in accordance with Article 61.

4. Devices that are manufactured and used within health institutions shall be considered as having been put into service.

5. With the exception of the relevant general safety and performance requirements set out in Annex I, the requirements of this Regulation shall not apply to devices, manufactured and used only within health institutions established in the Union, provided that all of the following conditions are met:

(a) the devices are not transferred to another legal entity,

(b) manufacture and use of the devices occur under appropriate quality management systems,

(c) the health institution justifies in its documentation that the target patient group's specific needs cannot be met, or cannot be met at the appropriate level of performance by an equivalent device available on the market,

(d) the health institution provides information upon request on the use of such devices to its competent authority, which shall include a justification of their manufacturing, modification and use;

(e) the health institution draws up a declaration which it shall make publicly available, including:

  (i) the name and address of the manufacturing health institution;

  (ii) the details necessary to identify the devices;

  (iii) a declaration that the devices meet the general safety and performance requirements set out in Annex I to this Regulation and, where applicable, information on which requirements are not fully met with a reasoned justification therefor,

(f) the health institution draws up documentation that makes it possible to have an understanding of the manufacturing facility, the manufacturing process, the design and performance data of the devices, including the intended purpose, and that is sufficiently detailed to enable the competent authority to ascertain that the general safety and performance requirements set out in Annex I to this Regulation are met;

(g) the health institution takes all necessary measures to ensure that all devices are manufactured in accordance with the documentation referred to in point (f), and

(h) the health institution reviews experience gained from clinical use of the devices and takes all necessary corrective actions.

Member States may require that such health institutions submit to the competent authority any further relevant information about such devices which have been manufactured and used on their territory. Member States shall retain the right to restrict the manufacture and the use of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions.

This paragraph shall not apply to devices that are manufactured on an industrial scale.

6. In order to ensure the uniform application of Annex I, the Commission may adopt implementing acts to the extent necessary to resolve issues of divergent interpretation and of practical application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).