BRITISH JOURNAL OF HOSPITAL MEDICINE

The impact of medical device regulation on hospital doctors who prescribe and manufacture custom-made devices

The 1990s saw the implementation of three European directives that aimed to standardise medical device legislation. EU regulations replace and repeal these directives, to improve the safety, effectiveness and traceability of medical devices. This article discusses the implications of the Regulation (EU) 2017/745 (Medical Device Regulation) for hospital doctors who prescribe and manufacture custom-made medical devices.

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How to cite this article: Green JIJ. The impact of medical device regulation on hospital doctors who prescribe and manufacture custom-made devices. Br J Hosp Med. 2020. https://doi.org/10.12968/hmed.2020.0596

Introduction

The 1990s saw the implementation of three directives that aimed to standardise medical device legislation within the EU:

1. Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (Active Implantable Medical Devices Directive) (Council of the European Communities, 1990)
2. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (Medical Device Directive) (Council of the European Communities, 1993)
3. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (In Vitro Diagnostic Medical Devices Directive) (European Parliament/European Council, 1998).

These directives, and their amendments, were transposed into UK legislation by The Medical Devices Regulations 2002 (SI 2002/618) and later amendments.

Medical device regulation

In the years that followed, incidents with sub-standard devices, notably the DePuy ASR XL Acetabular metal-on-metal hip replacement system (Cohen, 2012; Scientific Committee on Emerging and Newly Identified Health Risks, 2014) and Poly Implant Prothèse breast implants (Berry, 2007), identified weaknesses in the legislation. This ultimately led to the publication of Regulation (EU) 2017/745 (Medical Device Regulation), which replaces and repeals the Active Implantable Medical Devices Directive and the Medical Devices Directive and Regulation (EU) 2017/746 (In Vitro Diagnostic Medical Device Regulation) (European Parliament/European Council, 2017a, 2017b), which replaces and repeals the In Vitro Diagnostic Medical Devices Directive.

Full implementation of the EU Medical Device Regulation was scheduled for 26 May 2020 (European Parliament/European Council, 2017a). Aiming to avoid placing additional burdens upon medical device manufacturers during the coronavirus disease 2019 (COVID-19) pandemic, Regulation (EU) 2020/561 was adopted, which postponed this until 26 May 2021 (European Parliament/European Council, 2020). The In Vitro Diagnostic Medical Device Regulation is scheduled to repeal and replace the In Vitro Diagnostic Medical Devices Directive on 26 May 2022 (European Parliament/European Council, 2017b).

The UK left the EU on 31 January 2020 and entered an 11-month implementation period, during which EU legislation continues to apply. This is due to end on 31 December 2020 and full implementation of EU Medical Device Regulation and EU In Vitro Diagnostic Medical Device Regulation will fall outside this period. In preparation for the UK's departure from the EU, Regulation 2017/745 was largely transposed into the Medical Devices (Amendment etc.) (EU Exit) Regulations, 2019 (UK Medical Device Regulation, an amendment to The Medical Devices Regulations 2002; SI 2002/618), which was scheduled to come into effect on exit day. This has been further amended by the Medical Devices (Amendment etc.) (EU Exit)

Table 1. Health institution exemption conditions

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices Article 5	The Medical Devices (Amendment etc.) (EU Exit) Regulations, 2019; SI 2019/791 Regulation 71(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:	With the exception of the relevant safety and performance requirements set out in Schedule 3, the requirements of this Part do not apply to a device which is manufactured and used only within health institutions provided that:
1. The devices are not transferred to another legal entity	1. The device is not transferred to another legal entity
2. Manufacture and use of the devices occur under appropriate quality management systems	2. Manufacture and use of the device occurs under appropriate quality management systems
3. 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	3. 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
4. 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	4. On request from the Secretary of State, the health institution provides the Secretary of State with information (which must include justification for its manufacturing, modification and use of such devices) on the use of the devices
5. The health institution draws up a declaration which it shall make publicly available, including:	5. The health institution draws up and makes publicly available a statement setting out:
a. The name and address of the manufacturing health institution	a. The name and address of the manufacturing health institution
b. The details necessary to identify the devices	b. The details necessary to identify the devices
c. 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	c. A declaration that the devices meet the general safety and performance requirements set out in Schedule 3 or, where applicable, information on which requirements are not fully met and a reasoned justification for not meeting those requirements
6. 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	6. The health institution draws up a document which makes it possible to have an understanding of the manufacturing facility, the manufacturing process, the design and performance data of the devices and the intended purpose, and which is sufficiently detailed to enable the Secretary of State to ascertain whether the general safety and performance requirements set out in Schedule 3 are met
7. The health institution takes all necessary measures to ensure that all devices are manufactured in accordance with the documentation referred to in point (6), and	7. The health institution takes all necessary measures to ensure that the device is manufactured in accordance with the documentation referred to in sub-paragraph (6)
8. The health institution reviews experience gained from clinical use of the devices and takes all necessary corrective actions	8. The health institution reviews experience gained from the clinical use of the devices and takes all necessary corrective actions

Regulations 2020, which substitutes 'exit day' for 'implementation period completion day' and is expected to come into effect once EU law no longer applies, on 1 January 2021. This only applies to Great Britain; Northern Ireland is expected to remain in line with the EU legislation and implementation dates (Medicines and Healthcare products Regulatory Agency, 2020).

Custom-made devices

Hospital doctors prescribe and manufacture an array of custom-made devices such as auricular splints (Vercruysse et al, 2018), dental appliances, hearing aid inserts, joint

replacement implants, orthotics and prostheses (Medicines and Healthcare products Regulatory Agency, 2013). The Medical Device Regulation defines a manufacturer as someone 'who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark' (EU Medical Device Regulation Article 2/UK Medical Device Regulation Regulation 69). A doctor who prescribes a custom-made device 'has a device designed, manufactured or fully refurbished', so fulfils this role, at least in part.

The Medical Devices Directive had no regulatory requirements for medical devices prescribed and manufactured within a hospital for patients within that establishment – they were not considered to have been placed on the market, so were therefore exempt from the obligations (Medicines and Healthcare products Regulatory Agency, 2014). This is not the case under the Medical Device Regulation, and UK hospitals that wish to maintain such an exemption will need to satisfy the conditions laid out in EU Medical Device Regulation Article 5(5)/UK Medical Device Regulation Regulation 71(5) (Table 1).

From 1 January 2021, all medical devices will need to be registered with the Medicines and Healthcare products Regulatory Agency before being placed on the market in Great Britain. A grace period has been granted for this, which varies according to the device's risk class (Table 2). This grace period does not apply to devices placed on the Northern Ireland market (Medicines and Healthcare products Regulatory Agency, 2020).

Medical device manufacturers will need to appoint a Person Responsible for Regulatory Compliance under the Medical Device Regulation. The Person Responsible for Regulatory Compliance concept was inspired by the 'Qualified Person' in pharmaceuticals, a named person who is responsible for quality assurance of medicines. EU Medical Device Regulation Article 15 and UK Medical Device Regulation Regulation 80 provide the Person Responsible for Regulatory Compliance obligations.

Under the Medical Devices Directive, all medical devices must comply with the Essential Requirements set out in Annex I. Under the Medical Device Regulation, these have been replaced by the General Safety and Performance Requirements, which are given in EU Medical Device Regulation Annex I and UK Medical Device Regulation Schedule 3. The Essential Requirements and General Safety and Performance Requirements are broadly comparable, but have been expanded and include the obligation to establish, implement, document and maintain a risk management system. Quality management obligations are also more rigorous than under the Medical Devices Directive and are provided in EU Medical Device Regulation Article 10(9) and UK Medical Device Regulation Regulation 76(13–14).

Under the Medical Devices Directive, custom-made device manufacturers are required to follow the procedure set out in Medical Devices Directive Annex VIII. This is

Table 2. Grace period for registering with the Medical Healthcare products Regulatory Agency

Grace period in months (from 1 January 2021)	Medical devices
4	All active implantable medical devices
	Class III medical devices
	Class IIb implantable medical devices
	List A in vitro diagnostic medical devices
8	Other Class IIb medical devices
	All Class IIa medical devices
	List B in vitro diagnostic medical devices
	Self-test in vitro diagnostic medical devices
12	Class I medical devices*
	General in vitro diagnostic medical devices*

Does not apply to manufacturers of Class I devices and general in vitro diagnostic medical devices that are currently required to register with the Medicines and Healthcare products Regulatory Agency. From Medicines and Healthcare products Regulatory Agency (2020)

Table 3. Legislative requirements that concern custom-made devices

Requirement		Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices	The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019
1.	Register with the Medicines and Healthcare products Regulatory Agency	Article 21, paragraph 2	Regulation 86, paragraph 4
2.	Appoint a person responsible for regulatory compliance	Article 15	Regulation 80
3.	Manufacturers outside Great Britain placing devices on the UK market: appoint a UK responsible person	–	Regulation 77
	Manufacturers outside the EU or Northern Ireland placing devices on the EU or Northern Ireland market: appoint an authorised representative in the EU or Northern Ireland	Article 11	–
4.	Establish, document, implement and maintain, keep up to date and continually improve a quality management system	Article 10, paragraph 9	Regulation 76, paragraphs 13–14
5.	Comply with Annex I/Schedule 3 requirements applicable to custom-made devices (this includes: establish, implement, document and maintain a risk management system)	Article 5, paragraph 2	Regulation 71, paragraph 2
		Article 10, paragraph 2	Regulation 76, paragraph 2
		Annex I	Schedule 3
6.	Prepare technical documentation	Annex XIII, sections 2–3	Schedule 13, paragraphs 2–3
7.	Prepare statement of manufacture	Article 21, paragraph 2	Regulation 86, paragraph 3
		Annex XIII, section 1	Schedule 13, paragraph 1
8.	Retain copy of the statement of manufacture	Annex XIII, section 4	Schedule 13, paragraph 4
9.	Review and document experience gained in the post-production phase	Annex XIV, sections 5–8	Schedule 14, paragraphs 4–7
		Annex XIII, section 5	Schedule 13, paragraph 6
10.	Report serious incidents and field safety corrective actions	Article 87, paragraph 1	Regulation 125

comparable with EU Medical Device Regulation Annex XIII and UK Medical Device Regulation Schedule 13, but with minor changes: The statement of manufacture that must be provided with custom-made devices has some additional requirements and a copy of the statement needs to be retained for at least 10 years, rather than 5 years. In addition, manufacturers must continue to prepare documentation regarding the design, manufacture and performance of the devices they produce (which must be kept available for the Medicines and Healthcare products Regulatory Agency), review and document experience gained in the post-production phase, and report serious incidents and field safety corrective actions. Table 3 provides an overview of the legislative obligations that concern custom-made devices.

Conclusions

Hospital doctors need to be aware of the imminent legislative changes regarding custom-made devices. This article provides an overview of the relevant changes but is not intended to be a substitute to reading the legislation itself.

Key points

- The COVID-19 pandemic has led to a 1-year postponement of the full implementation of the EU Medical Device Regulation.
- The EU Medical Device Regulation has been largely transposed into UK law and is expected to take effect once EU legislation ceases to apply on 1 January 2021.
- A doctor who prescribes a custom-made device is, at least in part, the manufacturer of the device.
- Devices that are prescribed, manufactured and fitted within the same health institution will be considered as having been put into service under the new legislation.

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References

Berry RB. Rupture of PIP breast implants. J Plast Reconstr Aesthet Surg. 2007;60(8):967–968. https://doi.org/10.1016/j.bjps.2007.01.069

Cohen D. Faulty hip implant shows up failings of EU regulation. BMJ. 2012;345:e7163. https://doi.org/10.1136/bmj.e7163

Council of the European Communities. Council Directive 90/385/EEC of 20th June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices. 1990. https://www.emergobyul.com/sites/default/files/file/europe-consolidated-90-385-eec.pdf (accessed 20 November 2020)

Council of the European Communities. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. 1993. https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:en:PDF (accessed 20 November 2020)

European Parliament/European Council. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. 1998. https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1998L0079:20090807:EN:PDF (accessed 20 November 2020)

European Parliament/European Council. 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. 2017a. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745 (accessed 20 November 2020)

European Parliament/European Council. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing directive 98/79/EC and Commission Decision 2010/227/EU. 2017b. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0746&rid=6 (accessed 20 November 2020)

European Parliament/European Council. Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions. 2020. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX%3A32020R0561&from=EN (accessed 20 November 2020)

Medicines and Healthcare products Regulatory Agency. Custom-made devices. 2013. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/398428/Custom_made_devices.pdf (accessed 20 November 2020)

Medicines and Healthcare products Regulatory Agency. In-house manufacture of medical devices. 2014. https://www.gov.uk/government/publications/in-house-manufacture-of-medical-devices/in-house-manufacture-of-medical-devices (accessed 20 November 2020)

Medicines and Healthcare products Regulatory Agency. Regulating medical devices from 1 January 2021. 2020. https://www.gov.uk/guidance/regulating-medical-devices-from-1-january-2021 (accessed 20 November 2020)

Scientific Committee on Emerging and Newly Identified Health Risks. Opinion on the safety of metal-on-metal joint replacements with a particular focus on hip implants. 2014. https://ec.europa.eu/health/sites/health/files/scientific_committees/emerging/docs/scenihr_o_042.pdf (accessed 20 November 2020)

The Medical Devices (Amendment etc.) (EU Exit) Regulations. Statutory instrument 2019/791. 2019. https://www.legislation.gov.uk/uksi/2019/791/made/data.pdf (accessed 20 November 2020)

The Medical Devices (Amendment etc). (EU Exit) Regulations 2020. https://www.legislation.gov.uk/ukdsi/2020/9780348214956/pdfs/ukdsi_9780348214956_en.pdf (accessed 20 November 2020)

Vercruysse Jr H, Green JIJ, Osman G et al. Splinting after ear reconstruction: a stepwise and inexpensive workflow protocol. Ann Plast Surg. 2018;80(4):356–358. https://doi.org/10.1097/SAP.0000000000001212