EXPLANATORY MEMORANDUM TO

THE MEDICAL DEVICES (AMENDMENT) REGULATIONS 2013

2013 No. 2327

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

This memorandum contains information for the Joint Committee on Statutory Instruments

2. Purpose of the instrument

2.1 This instrument implements two European Union (EU) Regulations on the use of animal tissues and the provision of instructions for use in electronic form in connection with medical devices. It does so by making the provisions of the EU Regulations enforceable in the UK.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 In its Sixth Report of Session 2012-13, the JCSI drew special attention to the Medical Devices (Amendment) Regulations 2012 (S.I. 2012/1426) on the ground that regulation 3 (review) was defectively drafted. In response the Department undertook to make an appropriate amendment.

3.2 Regulation 18 of the Regulations provides for the review of the Medical Devices Regulations 2002 (as amended). In light of this new review provision, regulation 22 of these Regulations revokes the defective provision at regulation 3 of S.I. 2012/1426.

4. Legislative Context

4.1 The Medical Devices Regulations 2002 transpose three main EU Directives covering the safety of medical devices on the market in the UK:

i. Directive 90/385/EEC on active implantable medical devices (AIMDD);
ii. Directive 93/42/EEC on medical devices (MDD); and
iii. Directive 98/79/EC on in vitro diagnostic medical devices (IVDD).

4.2 EU Regulation 722/2012 on the use of certain animal tissues in medical devices and EU Regulation 207/2012 on the provision of instructions for use in electronic form supplement these three framework Directives. Both EU Regulations were agreed under comitology and as such have not been subject to any Parliamentary scrutiny.

5. Territorial Extent and Application

5.1 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

As the instrument is subject to the negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

- *What is being done and why*

7.1 Firstly, the EU Regulation on animal tissues replaces the existing EU rules (Directive 2003/32/EC), which aim to protect public health and minimise the possibility of infecting humans with Transmissible Spongiform Encephalopathies (TSEs) from the use of medical devices manufactured utilising animal tissues. The Regulation aims to bear down on the small risk posed to the public from the use of these tissues in medical devices, by updating these rules in line with global experience and addressing the current lack of consistency by extending the scope of the precautionary measures to cover active implantable medical devices (general medical devices are already covered by the existing requirements).

7.2 Secondly, the EU Regulation on the provision of instructions for use in electronic form gives manufacturers of certain medical devices the option to supply instructions for use for their products in electronic form, so long as they comply with certain rules, which aim to ensure patient safety. For example, manufacturers must carry out a risk assessment of switching to electronics instructions for use. The EU Regulation aims to reduce costs on medical devices manufacturers, reduce the environmental burden, and improve some aspects of safety by, for example, allowing swifter updating of instructions for use that is simpler to achieve when they are provided in electronic form.

7.3 These changes are not politically or legally important.

- *Consolidation*

7.4 There is no intention to consolidate the relevant legislation at this time because the European Commission have proposed a revision to the regulatory framework for medical devices[*]. The intention is for two EU Regulations to replace the three Directives set out at paragraph 4.1; the adoption of these Regulations will lead to the repeal of the Medical Devices Regulations 2002. The two proposed EU Regulations are currently under negotiation by the European Parliament and Council and are subject to Parliamentary scrutiny.

[*] http://ec.europa.eu/health/medical-devices/documents/revision/index_en.htm

8. Consultation outcome

8.1 A targeted, four-week public consultation was held in April/May 2013 seeking views on the proposed approach to this instrument and of the impacts of the changes[†]. This shorter timescale was appropriate given the direct applicability of the Regulations in UK law, the highly technical and specialised nature of Regulations and the limited number of interested stakeholders.

8.2 Only two responses to the consultation were received, neither of which raised concerns with the proposed approach. Thus the Department did not amend its approach in light of the public consultation.

9. Guidance

9.1 The Medicines and Healthcare products Regulatory Agency (MHRA) has already communicated the changes directly to known stakeholders that will be affected by the changes. The MHRA's website will also be updated to reflect the changes.

10. Impact

10.1 The EU Regulation on animal tissues has a very low cost to business; there will be an additional ongoing cost impact of a maximum of £24,000 per annum for the fewer than 10 affected UK medical devices manufacturers. This aspect of the Medical Devices (Amendment) Regulations qualified for assessment through the Regulatory Policy Committee's (RPC) fast-track process and the Department's assessment was confirmed by the RPC. This impact is negligible in the context of a sector with a turnover of £13bn in the UK.

10.2 The EU Regulation on the provision of instructions for use in electronic form has the potential to be deregulatory for the 3,100 medical devices manufacturers in the UK, who can now choose to replace paper instructions for use with electronic instructions for use for certain categories of devices where they identify a benefit to doing so.

10.3 Whilst this aspect of the Medical Devices (Amendment) Regulations is a deregulatory measure and so would also qualify for the RPC's fast-track, the MHRA are assessing this measure under the new Accountability for Regulator Impact (ARI) process. The outcome of this assessment will be published in due course.

10.4 There is no impact on the public sector.

11. Regulating small business

11.1 The legislation applies to small business. As the legislation implements two EU Regulations the Government does not have discretion to

[†] http://www.mhra.gov.uk/Publications/Consultations/Deviceconsultations/CON261771

minimise the impact on small business. As set out previously, however, the expected impact of the measure on businesses is minimal.

12. Monitoring & review

12.1 The Secretary of State is required to review the 2002 Regulations and publish a report by the end of 31st December 2019.

13. Contact

13.1 Graeme Tunbridge at the Medicines and Healthcare products Regulatory Agency (MHRA) Tel: 020 3080 6554 or email: graeme.tunbridge@mhra.gsi.gov.uk can answer any queries regarding this instrument.