EXPLANATORY MEMORANDUM TO

THE MEDICAL DEVICES (AMENDMENT) REGULATIONS 2012

2012 No. 1426

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

2. Purpose of the instrument

2.1 The instrument places medical devices used to identify the presence of variant Creutzfeldt-Jakob Disease (vCJD) in human blood into the regulatory category subject to the highest possible level of scrutiny before being placed on the market. This level of scrutiny is required because of the potential of an incorrect diagnosis to have significant personal and public health consequences.

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

3.1 None

4. Legislative Context

4.1 This instrument implements the requirements of Directive 2011/100/EU, which amends Annex II of Directive 98/79/EC concerning *in vitro* diagnostic medical devices by placing vCJD assays for blood screening, diagnosis and confirmation into List A of that Annex.

4.2 Directive 98/79/EC has been transposed into UK legislation through the Medical Devices Regulations 2002, although the technical annexes to the Directive have not been directly transposed and relevant references are made to the annexes within the 2002 Regulations.

4.3 Directive 2011/100/EU is given effect by amending the 2002 Regulations such that they specify that any reference within the 2002 Regulations to the technical annexes of Directive 98/79/EC refers to those annexes as amended from time to time. Such a change also means that further changes to the technical annexes of Directive 98/79/EC will not require a further transposition exercise.

4.4 This instrument makes the same change to the 2002 Regulations for Directives 90/385/EEC and 93/42/EEC concerning active implantable medical devices and medical devices respectively.

4.5 This instrument also amends the references to Directives 90/385/EEC and 93/42/EEC in the 2002 Regulations to provide a legal clarification

that Directive 2007/47/EC amends those Directives. Directive 2007/47/EC was given effect previously through the Medical Devices (Amendment) Regulations 2008.

4.6 A transposition note is attached to this memorandum.

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 negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

- ***What is being done and why***

7.1 In 2007, the Medicines and Healthcare products Regulatory Agency (MHRA) made a duly substantiated request under Directive 98/79/EC to reclassify vCJD assays into the highest risk classification. This was undertaken following a request by the Department of Health who had received recommendations from the UK Advisory Committee on the Microbiological Safety of Blood, Tissues and Organs and the Spongiform Encephalopathy Advisory Committee. Both Committees were concerned that new assays under development to diagnose the presence of vCJD in donated blood could, at that time, be available on the European market within 12-18 months and because of the public health implications should be subject to the highest possible regulatory scrutiny. In the absence of reclassification such assays would *de facto* come under the lowest risk category in Directive 98/79/EC.

7.2 Directive 98/79/EC lays down common requirements concerning the safety, quality and performance of diagnostic tests that a manufacturer must meet before placing them on the market in the EU. It groups diagnostic assays into four categories according to the risks associated with the relative dangers to public health and/or patient treatment by an assay failing to perform as intended. The highest risk category is Annex II List A which includes tests for HIV, hepatitis and some blood grouping products, including those to test donated blood. This risk category has the most stringent requirements to assure the performance of an assay before it is placed on the market. It is this highest risk category into which vCJD assays have been placed by Directive 2011/100/EU because incorrect diagnosis of vCJD would not only be highly detrimental to a patient but could also result in damage to the donor base and have an adverse impact on the blood supply.

7.3 Although it was anticipated in 2007 that vCJD assays could be available on the European market within 12-18 months, this did not

transpire and there are currently not any such devices on the market anywhere worldwide.

- ***Consolidation***

7.4 There is no intention to consolidate the relevant legislation at this time as the European Commission are expected to adopt legislation revising Directives 90/385/EEC, 93/42/EEC and 98/79/EC in September 2012.

8. Consultation outcome

8.1 A targeted, four-week consultation was held in March/April 2012 seeking views on the proposed approach to transposition of Directive 2011/100/EU and of the impacts of the changes[*]. This shorter timescale was appropriate given the highly technical and specialised nature of the amendment to Directive 98/79/EC and the limited number of stakeholders with an interest. It also reflects the relatively short period of a little over six months between publication of Directive 2011/100/EU in the Official Journal of the European Union (OJEU) and the transposition deadline.

8.2 Only a small number of responses were received; these did not express any concerns with the approach to transposition and confirmed the MHRA's understanding of the current status of commercial vCJD assays.

9. Guidance

9.1 The MHRA will communicate 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 There is no immediate impact on business, charities or voluntary bodies as there are not currently any vCJD assays on the market. Owing to the nature of scientific progress, it is very difficult to speculate when vCJD assays will be commercially available; consultation responses indicated that this is likely to be a minimum of two years.

10.2 We have, however, been able to estimate the notional impact of implementing Directive 2011/100/EU based on the typical additional costs borne by a manufacturer for a device placed in Annex II List A of Directive 98/79/EC compared to a device not requiring any specific pre-market scrutiny. Per assay we would estimate a one-off cost of between £12,000 and £18,000 and annual costs of between £9,000 and £10,000.

[*] See http://www.mhra.gov.uk/Howweregulate/Devices/Devicesregulatorynews/CON146619

10.3 There is no impact on the public sector.

10.4 An Impact Assessment is attached to this memorandum and will be published alongside the Explanatory Memorandum on www.legislation.gov.uk. The Impact Assessment was given a 'green' rating by the Regulatory Policy Committee.

11. Regulating small business

11.1 The legislation applies to small business.

12. Monitoring & review

12.1 The European Commission are expected to adopt legislation revising Directive 98/79/EC in September 2012. It is expected that the Directive will be replaced by a Regulation and that significant changes will be made to the legislation. As such, no separate monitoring or review of this instrument is anticipated.

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 the instrument.

Annex

Transposition note for Directive 2011/100/EU amending Directive 98/79/EC on *in-vitro* diagnostic medial devices

Directive 2011/100/EU is being transposed into UK legislation through the Medical Devices (Amendment) Regulations 2012. These regulations do what is necessary to implement the Directive, including making consequential changes to domestic legislation to ensure its coherence in the area to which they apply.

Article	Objective	Implementation	Responsibility
1	Adds vCJD assays for blood screening, diagnosis and confirmation to List A of Annex II of Directive 98/79/EC on *in-vitro* diagnostic medical devices.	Regulation 2(b) of the Medical Devices (Amendment) Regulations 2012 adds an ambulatory reference to the annexes of Directive 98/79/EC to the Medical Devices Regulations 2002 such that they refer to the annexes *as amended from time to time*. This will also mean that future changes to the annexes to the Directive do not need to be transposed.	Secretary of State