SCHEDULE 1

Amendment of the Medical Devices Regulations 2002

Substitution of regulation 44

15. For regulation 44 (registration of manufacturers etc. of *in vitro* diagnostic medical devices and devices for performance evaluation) substitute—

"**Registration of persons placing in vitro diagnostic medical devices on the market or for performance evaluation**

44.—(1) Paragraph (2) applies—

(a) in relation to relevant devices that are Annex II devices or devices for self-testing, to—

(i) a manufacturer with a registered place of business in Northern Ireland who, under their own name, places on the market in Northern Ireland, or makes available for performance evaluation, any relevant device;

(ii) a UK responsible person;

(iii) a manufacturer's authorised representative who has a registered place of business in Northern Ireland;

(iv) a manufacturer with a registered place of business in Great Britain whose authorised representative does not have a registered place of business in Northern Ireland;

(b) in relation to relevant devices other than Annex II devices or devices for self-testing, to—

(i) a manufacturer who places a device on the Northern Ireland market, or makes such a device available for performance evaluation, and has a registered place of business in Northern Ireland;

(ii) an authorised representative with a registered place of business in Northern Ireland.

(2) For the purpose of enabling the Secretary of State to exercise the Secretary of State's functions under these Regulations, any person to whom this paragraph applies must—

(a) inform the Secretary of State of the address of their registered place of business; and

(b) supply the Secretary of State with—

(i) a description of each category of device concerned;

(ii) the relevant information in paragraph (7);

(c) in the case of a UK responsible person, supply the Secretary of State with—

(i) written evidence that they have been appointed as a UK responsible person;

(ii) details of the person who has appointed them; and

(iii) where the person placing the devices concerned on the market is neither the manufacturer nor the UK responsible person, the name and address of the registered place of business of the person placing the devices concerned on the market;

(d) in the case of an authorised representative, supply the Secretary of State with—

(i) written evidence that they have been designated as an authorised representative;

(ii) details of the person who has so designated them; and

(iii) where the person placing the devices concerned on the market, or making them available for performance evaluation, is neither the manufacturer nor the authorised representative, the name and address of the registered place of business of the person placing the devices concerned on the market, or making them available for performance evaluation;

(e) inform the Secretary of State of any changes to the information referred to in sub-paragraphs (a) to (d) as and when such changes arise.

(3) The obligation in paragraph 2(2)(e) to inform the Secretary of State of any changes in relation to the information referred to in sub-paragraphs (2)(a) to (d) continues to apply following the passing of any of the dates specified in paragraph (4) that apply in respect of a particular case.

(4) The obligations in paragraph (2) begin to apply—

(a) where a device is being placed on the market by a manufacturer with a registered place of business in Northern Ireland or by a person who has designated an authorised representative with a registered place of business in Northern Ireland, on 1st January 2021;

(b) in circumstances other than those described in sub-paragraph (a)—

(i) in the case of a relevant device that is a List A device, on 1st May 2021;

(ii) in the case of a relevant device that is a device for self-testing, on 1st September 2021; and

(iii) in the case of a relevant device that is a List B device, on 1st September 2021.

(5) A UK responsible person must—

(a) ensure that the declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;

(b) keep available for inspection by the Secretary of State a copy of the technical documentation, a copy of the declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements;

(c) in response to a request from the Secretary of State, provide the Secretary of State with all the information and documentation necessary to demonstrate the conformity of a device;

(d) where they have samples of the device or access to the device, comply with any request from the Secretary of State to provide such samples or access;

(e) where they have neither samples of the device nor access to the device, communicate to the manufacturer any request from the Secretary of State to provide such samples or access, and communicate to the Secretary of State whether the manufacturer intends to comply with that request;

(f) cooperate with the Secretary of State on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;

(g) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been appointed;

(h) if the manufacturer acts contrary to its obligations under these Regulations—

(i) terminate the legal relationship with the manufacturer; and

(ii) inform the Secretary of State and, if applicable, the relevant notified body of that termination.

(6) In this regulation the references to "technical documentation" and "declaration of conformity" are to be construed in accordance with Directive 98/79.

(7) In this regulation "relevant information" means—

(a) in relation to a new relevant device, a statement indicating that the device is a new relevant device;

(b) if the device consists wholly or partly of reagents, reagent products or calibration and control materials, appropriate information in terms of common technological characteristics and analytes;

(c) if the device does not wholly or partly consist of reagents, reagent products or calibration and control materials, the appropriate indications;

(d) in relation to devices in a list in Annex II and devices for self-testing—

(i) all data allowing for identification of such devices, the analytical and, where appropriate, diagnostic parameters as referred to in Section 3 of Part A of Annex 1;

(ii) if requested by the Secretary of State, the labelling and instructions for use for when the device is placed on the market or put into service;

(e) in relation to devices for performance evaluation which relate either to devices referred to in a list in Annex II or to devices for self-testing, all data allowing for identification of such devices, the analytical and where appropriate, diagnostic parameters as referred to in Section 3 of Part A of Annex I.

(8) Within two years of the placing of a new relevant device on the market, the Secretary of State may, where the Secretary of State considers it justified, request a report relating to the experience gained with the device subsequent to it being placed on the market.

(9) In paragraphs (7) and (8) a device is a "new relevant device" if—

(a) there has been no such device continuously available on the United Kingdom or EEA market during the previous three years for the relevant analyte or other parameter; or

(b) use of the device has involved analytical technology not continuously used in connection with a given analyte or other parameter on the United Kingdom or EEA market during the previous three years.

Requirement to appoint a UK responsible person for placing in vitro diagnostic medical devices on the market or for performance evaluation

44ZA.—(1) Paragraph (2) applies in relation to a manufacturer who—

(a) does not have a registered place of business in the United Kingdom;

(b) has not designated an authorised representative who has a registered place of business in Northern Ireland; and

(c) places a relevant device a device that is an Annex II device or a device for self-testing, on the market in Northern Ireland; or

(d) makes available such a device for performance evaluation.

(2) A manufacturer to whom this paragraph applies must appoint a person with a registered place of business in the United Kingdom as their UK responsible person to carry out the tasks described in regulations 44(2) and (5).".