SCHEDULE 1 Regulation 2

Amendment of the Medical Devices Regulations 2002

1. The Medical Devices Regulations 2002 are amended in accordance with this Schedule.

Amendment of regulation 2

2. In regulation 2 (interpretation)—

(a) for the definition of "authorised representative" substitute—

""authorised representative" means a person established within a relevant state, explicitly designated by the manufacturer who is not a person established in a relevant state, who acts for the manufacturer and may be addressed by authorities and bodies in a relevant state instead of the manufacturer with regard to the latter's obligation under Directive 90/385, Directive 93/42 and Directive 98/79;";

(b) in the definition of "EC CAB" omit "EC";

(c) in the definition of "intended for clinical investigation", in paragraph (b) for "Member State" substitute "relevant state";

(d) in the definition of "national standard" for "a Member State of the Community" substitute "a relevant state";

(e) in the definition of "placing on the market", for "the Community market" substitute "a relevant market";

(f) in paragraph (b) of the definition of "putting into service" for "the Community" substitute "a relevant state";

(g) in the appropriate places insert—

""relevant market" means a market of a relevant state;";

""relevant state" means—

(a) in relation to any requirement relating to an *in vitro* diagnostic medical device, Northern Ireland or a Member State of the European Union;

(b) in relation to any requirement relating to any other medical device, Northern Ireland or a state in the European Economic Area;

(c) a State other than a Member State of the European Union which is a Party to an Association Agreement (where applicable under that Association Agreement);";

""UK mutual recognition agreement" means an agreement between the United Kingdom and another country that covers matters including the conditions under which the United Kingdom and that country will accept or recognise the results of the conformity assessment procedures undertaken by each other's designated bodies;";

""UK(NI) indication" means the marking in the form set out in Schedule 1 to the Product Safety and Metrology etc. (Amendment etc.) (UK(NI) indication) (EU Exit) Regulations 2020;";

""UK responsible person" is to be construed in accordance with regulation 19B(2) for the purposes of Part II, regulation 21C(2) for the purposes of Part III and regulation 44A(2) for the purposes of part IV.".

Insertion of regulation 10A

3. After regulation 10 (CE marking of general medical devices) insert—

"**UK(NI) indication: general medical devices**

10A.—(1) Where the CE marking referred to in regulation 10 is affixed on the basis of an assessment or a certificate issued by a notified body established in the United Kingdom, a UK(NI) indication must be affixed in relation to the device, in accordance with this regulation.

(2) The UK(NI) indication must be affixed—

(a) visibly, legibly and indelibly; and

(b) before a relevant device is placed on the market in Northern Ireland.

(3) The UK(NI) indication must accompany the CE marking, wherever such marking is affixed in accordance with regulation 13.

(4) The UK(NI) indication must be affixed by the manufacturer.

(5) Anyone who places a medical device on the market in Northern Ireland must ensure that the manufacturer has complied with their obligations under this regulation.

(6) No person shall supply a relevant device unless the manufacturer has affixed a UK(NI) indication as required by this regulation, if that supply is also a placing on the market or putting into service, or that supply is of a device that has been placed on the market or put into service.".

Amendment of regulation 16

4. In regulation 16(1) (procedures for general medical devices for clinical investigations), for "the United Kingdom" substitute "Northern Ireland".

Amendment of regulation 17

5. In regulation 17 (manufacturers etc and conformity assessment procedures for general medical devices) omit paragraph (3).

Substitution of regulation 19

6. For regulation 19 (registration of persons placing general medical devices on the market) substitute—

"**Registration of persons placing general medical devices on the market**

19.—(1) Paragraph (2) applies—

(a) in relation to relevant devices that are neither Class I devices nor custom-made devices, 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 any general medical device of any class, other than a system or procedure pack which is not CE marked;

(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 Class I devices and custom-made devices, to—

(i) a manufacturer who places a device on the Northern Ireland market and has a registered place of business in Northern Ireland;

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

(c) to a person with a registered place of business in Northern Ireland who sterilises before use any devices designed by their manufacturer to be sterilised before use.

(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 their address and registered place of business;

(b) supply the Secretary of State with a description of each category of device concerned;

(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 so 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 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;

(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) in the case of a device that is a Class I device and custom-made devices, on 1st January 2021;

(b) in the case of a device that is a Class III or IIb implantable device, on 1st May 2021;

(c) in the case of a device that is a Class IIa or Class IIb non-implantable 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 93/42.".

Insertion of regulation 19B

7. After regulation 19 insert—

"**Requirement to appoint a UK responsible person for general medical devices**

19B.—(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, other than a Class I or custom-made device, on the market in Northern Ireland.

(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 19(2) and (5).".

Insertion of regulation 21B

8. After regulation 21 (scope of Part III) insert—

"**Registration of persons placing active implantable medical devices on the market**

21B.—(1) Paragraph (2) applies—

(a) in relation to relevant devices other than custom-made devices, 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 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 that are custom-made devices, to—

(i) a manufacturer who places a device on the Northern Ireland market 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 a description of each category of device concerned;

(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 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;

(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 the date specified in paragraph (4).

(4) The obligations in paragraph (2) begin to apply on 1st May 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 90/385.

Requirement to appoint a UK responsible person for active implantable medical devices

21C.—(1) Paragraph (2) applies in relation to a manufacturer who—

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

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

(c) places a relevant device, other than a custom-made device, on the market in Northern Ireland.

(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 21B(2) and (5).".

Insertion of regulation 24A

9. After regulation 24 (CE marking of active implantable medical devices) insert—

"**UK(NI) indication: active implantable medical devices**

24A.—(1) Where the CE marking referred to in regulation 24 is affixed on the basis of an assessment or a certificate issued by a notified body established in the United Kingdom, a UK(NI) indication must be affixed in relation to the device, in accordance with this regulation.

(2) The UK(NI) indication must be affixed—

(a) visibly, legibly and indelibly; and

(b) before a relevant medical device is placed on the market in Northern Ireland.

(3) The UK(NI) indication must accompany the CE marking, wherever that is affixed in accordance with regulation 27.

(4) The UK(NI) indication must be affixed by the manufacturer.

(5) Anyone who places a medical device on the market in Northern Ireland must ensure that the manufacturer has complied with their obligations under this regulation.

(6) No person shall supply a relevant device unless the manufacturer has affixed a UK(NI) indication as required by this regulation, if that supply is also a placing on the market or putting into service, or that supply is of a device that has been placed on the market or put into service";".

Amendment of regulation 29

10. In regulation 29(1) (procedures for active implantable medical devices for clinical investigations) for "the United Kingdom" substitute "Northern Ireland".

Amendment of regulation 30

11. In regulation 30 (manufacturers etc. and conformity assessment procedures for active implantable devices)—

(a) in paragraph (4) for "a Member State" in both places substitute "a relevant state";

(b) in paragraph (5) for "the Member State" substitute "the relevant state".

Amendment of regulation 35

12. In regulation 35(2) (determining compliance of *in vitro* diagnostic medical devices with relevant essential requirements) for "the United Kingdom" substitute "Northern Ireland".

Insertion of regulation 36A

13. After regulation 36 (CE marking of *in vitro* diagnostic medical devices) insert—

"**UK(NI) indication: in vitro diagnostic medical devices**

36A.—(1) Where the CE marking referred to in regulation 36 is affixed on the basis of an assessment or a certificate issued by a notified body established in the United Kingdom, a UK(NI) indication must be affixed in relation to the device, in accordance with this regulation.

(2) The UK(NI) indication must be affixed—

(a) visibly, legibly and indelibly; and

(b) before a relevant medical device is placed on the market in Northern Ireland.

(3) The UK(NI) indication must accompany the CE marking, wherever that is affixed in accordance with regulation 36.

(4) The UK(NI) indication must be affixed by the manufacturer.

(5) Anyone who places a medical device on the market in Northern Ireland must ensure that the manufacturer has complied with their obligations under this regulation.

(6) No person shall supply a relevant device unless the manufacturer has affixed a UK(NI) indication as required by this regulation, if that supply is also a placing on the

market or putting into service, or that supply is of a device that has been placed on the market or put into service".".

Amendment of regulation 41

14. In regulation 41 (manufacturers etc and conformity assessment procedures for in vitro diagnostic medical devices), in paragraph (5), for "in the United Kingdom" substitute "in Northern Ireland".

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

44A.—(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).".

Amendment of regulation 45

16. In regulation 45(1) (designation etc. of UK notified bodies), after "any of the tasks of a notified body" insert "with respect to devices to be placed on the market in Northern Ireland".

Insertion of regulation 47A

17. After regulation 47 (general matters relating to UK notified bodies) insert—

"**Register of UK notified bodies**

47A.—(1) The Secretary of State must ensure that—

(a) each notified body established in the United Kingdom is assigned an identification number; and

(b) there is a register of—

(i) notified bodies established in the United Kingdom;

(ii) their notified body identification number;

(iii) the tasks for which they have been notified;

(iv) any restrictions on those tasks.

(2) The Secretary of State must ensure that the register referred to in paragraph (1) is maintained and made publicly available.

(3) The Secretary of State may authorise the United Kingdom Accreditation Service to compile and maintain the register in accordance with paragraph (1)(b).".

Amendment of regulation 48

18. In regulation 48 (designation etc. of EC conformity assessment bodies)—

(a) in the heading omit "EC";

(b) in paragraph (1)—

(i) for "the Mutual Recognition Agreements" substitute "a UK mutual recognition agreement";

(ii) omit "European Community";

(iii) for "an "EC CAB"" substitute "a "CAB"";

(c) in paragraph (2)—

(i) for "an EC CAB" in both places substitute "a CAB";

(ii) for "the Mutual Recognition Agreements" substitute "a UK mutual recognition agreement";

(d) in paragraph (4) for "an EC CAB" substitute "a CAB";

(e) in paragraph (5)—

(i) for "an EC CAB" substitute "a CAB";

(ii) for "the Mutual Recognition Agreements" substitute "a UK mutual recognition agreement";

(f) in paragraph (6) omit "EC" in both places;

(g) in paragraph (7)—

(i) for "an EC CAB" substitute "a CAB";

(ii) for "the Mutual Recognition Agreements" substitute "a UK mutual recognition agreement";

(h) in paragraph (8)—

(i) for "an EC CAB" in both places substitute "a CAB";

(ii) for "the Mutual Recognition Agreements" substitute "a UK mutual recognition agreement".

Amendment of regulation 49

19. In regulation 49 (fees charged by UK notified bodies and EC conformity assessment bodies)—

(a) for the heading substitute "Fees charged by UK notified bodies and conformity assessment bodies";

(b) in the opening words of paragraph (1) for "EC CAB" substitute "CAB";

(c) in paragraph (1)(a) for "the Medical Devices Directives or the Mutual Recognition Agreements in respect of a conformity assessment procedure set out in the Medical Devices Directives" substitute "the Medical Devices Directives or a UK mutual recognition agreement in respect of a conformity assessment procedure set out in the Medical Devices Directives or these Regulations as they apply in Great Britain";

(d) in paragraph (1)(b)—

(i) for "an EC CAB" in both places substitute "a CAB";

(ii) for "the Mutual Recognition Agreements" substitute "a UK mutual recognition agreement";

(e) in paragraph (3) for "EC CAB" substitute "CAB";

(f) in paragraph (4) for "EC CAB" substitute "CAB".

Amendment of regulation 53

20. In regulation 53 (fees in connection with the registration of devices and changes to registration details), after "regulation 19" insert ", 21B".

Amendment of regulation 55

21. In regulation 55 (fees payable in connection with the designation etc. of EC conformity assessment bodies)—

(a) in the heading, omit "EC";

(b) in paragraph (1), for "an EC CAB" substitute "a CAB";

(c) in paragraph (3)—

(i) for "an EC CAB" substitute "a CAB";

(ii) for "the Mutual Recognition Agreements" substitute "a UK mutual recognition agreement".

Amendment of regulation 58

22. In regulation 58(2)(b)(ii) (waivers, reductions and refunds), for "an EC CAB" substitute "a CAB".

Amendment of regulation 60

23. In regulation 60 (designation etc of authorised representatives)—

(a) in paragraph (1)—

(i) omit ", other than an obligation referred to in regulation 17(3),";

(ii) for "in the Community or (where appropriate) in a State which is a Party to an Association Agreement" substitute "in a relevant state";

(b) in paragraph (2)—

(i) for "in the Community or (where appropriate) in a State which is a Party to an Association Agreement" substitute "in a relevant state";

(ii) in sub-paragraph (a) for "in the Community" substitute "in a relevant state";

(c) in paragraph (3)—

(i) for "the Community" substitute "a relevant state";

(ii) in sub-paragraph (b)—

(aa) for "the United Kingdom" substitute "Northern Ireland";

(bb) for "the Community or in a State which is a Party to an Association Agreement" substitute "a relevant state".

Amendment of regulation 61

24. In regulation 61 (enforcement etc.)—

(a) after paragraph (1) insert—

"(1A) Paragraph (1) applies in relation to regulations 10A, 24A and 36A (UK(NI) indication) as it does in relation to any other provision of these Regulations to which it applies.".

(b) in paragraph (2) omit "each weights and measures authority in Great Britain and";

(c) in paragraph (3) omit "each weights and measures authority in Great Britain and";

(d) in paragraph (5) omit "authority and";

(e) in paragraph (6) omit sub-paragraphs (a) and (c).

Amendment of regulation 63

25. In regulation 63 (restriction notices)—

(a) in paragraph (4) omit "or a sheriff";

(b) in paragraph (5)—

(i) in the words before sub-paragraph (a) omit "or a sheriff";

(ii) in sub-paragraph (a) omit "or the sheriff";

(iii) in sub-paragraph (b) omit "or the sheriff";

(iv) in the words after sub-paragraph (b) omit "or the sheriff".

Amendment of regulation 65

26. In regulation 65 (centralised system of records etc.) for "the United Kingdom" substitute "Northern Ireland".