SCHEDULES

SCHEDULE 2

Amendment of the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

PART 2

Amendment of Part 3 (amendment of Part 3 (manufacture and distribution of medicinal products and active substances))

8. In regulation 13 (new regulation B17 and C17 (good manufacturing practice and good distribution practice))—

(a) in the inserted regulation B17—

(i) in paragraph (1)—

(aa) for "Ministers" substitute "Secretary of State";

(bb) after "by regulations" insert "in respect of Great Britain";

(ii) in paragraph (2)(b) after "UK marketing authorisation" insert "or EU marketing authorisation";

(iii) in paragraph (3)—

(aa) after "have effect" insert "in Great Britain";

(bb) for "exit day" in both places it occurs substitute "IP completion day";

(iv) in paragraph (4)—

(aa) for "Ministers" substitute "Secretary of State";

(bb) after "by regulations" insert "in respect of Great Britain";

(b) in the inserted regulation C17—

(i) in paragraph (1), after "may publish" insert "in relation to the manufacture or assembly of a medicinal product in, or import to, Great Britain";

(ii) in paragraph (3) for "exit day" in both places it occurs substitute "IP completion day".

9. In regulation 14 (amendment of regulation 17 (manufacturing of medicinal products))—

(a) for paragraph (2) substitute—

"(2) For paragraph (1) substitute—

"(1) A person may not except in accordance with a licence (a "manufacturer's licence")—

(a) manufacture a medicinal product,

(b) assemble a medicinal product,

(c) import a medicinal product into Great Britain from a country other than—

(i) Northern Ireland, or

(ii) an approved country for import,

(d) import a medicinal product into Northern Ireland from a country other than an EEA State, or

(e) possess a medicinal product for the purpose of any activity in sub-paragraphs (a) to (d).".";

(b) omit paragraph (3);

(c) for paragraph (4) substitute—

"(4) In paragraph (4), after sub-paragraph (a) insert—

"(aa) a UK marketing authorisation; or".";

(d) for paragraph (5) substitute—

"(5) In paragraph (5) omit "from a state other than an EEA State".";

(e) after paragraph (5) insert—

"(6) After paragraph (6) insert—

"(7) Paragraph (1) does not apply to imports into Northern Ireland from Great Britain of—

(a) special medicinal products, and

(b) medicinal products that have been released for sale, supply or distribution in an EEA State or the United Kingdom before IP completion day.

(8) For the purposes of paragraph (7) a medicinal product has been released for sale, supply or distribution where, after the stage of manufacturing has taken place, the product is the subject matter of a written or verbal agreement between two or more persons for the transfer of ownership, any other property right, or possession concerning the product, or where the product is the subject matter of an offer to a person to conclude such an agreement.".".

10. In regulation 15 (amendment of regulation 18 (wholesale dealing in medicinal products))—

(a) in paragraph (2)(c), in the inserted sub-paragraph (c)—

(i) after "medicinal product" insert "into Great Britain";

(ii) omit "for either purpose";

(b) after paragraph (2) insert—

"(2A) After paragraph (2) insert—

"(2A) Paragraph (1)(c) does not apply to imports into Great Britain from an EEA State of medicinal products that have been released for sale, supply or distribution in an EEA State or the United Kingdom before IP completion day.

(2B) For the purposes of paragraph (2A) a medicinal product has been released for sale, supply or distribution where, after the stage of manufacturing has taken place, the product is the subject matter of a written or verbal agreement between two or more persons for the transfer of ownership, any other property right, or possession concerning the product, or where the product is the subject matter of an offer to a person to conclude such an agreement.".";

(c) for paragraph (3) substitute—

"(3) For paragraph (6) substitute—

"(6) A wholesale dealer's licence does not authorise the distribution of a medicinal product by way of wholesale dealing, or possession of a medicinal product for the purpose of such distribution, unless—

(a) in the case of a product for sale or supply in Great Britain, a UKMA(GB) or UKMA(UK), certificate of registration or traditional herbal registration is in force in respect of the product, or

(b) in the case of a product for sale or supply in Northern Ireland, a UKMA(NI) or UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration is in force in respect of the product,

but this is subject to the exceptions in regulation 43(6).".";

(d) for paragraph (4) substitute—

"(4) In paragraph (7) for "paragraph (6)" substitute "paragraph (6)(b)".".

11. In regulation 17 (amendment of regulation 19 (exemptions from requirement for wholesale dealer's licence))—

(a) for paragraph (2) substitute—

"(2) For paragraph (1)(a) substitute—

"(a) the holder of—

(i) in the case of a product for sale or supply in Great Britain, a UKMA(GB), a UKMA(UK), a COR(GB), a COR(UK), a THR(GB) or a THR(UK) (an "authorisation") which relates to the product, or

(ii) in the case of a product for sale or supply in Northern Ireland, a UKMA(NI), a UKMA(UK), a COR(NI), a COR(UK), a THR(NI), a THR(UK), an EU marketing authorisation or an Article 126a authorisation (an "authorisation") which relates to the product,

including a holder of an authorisation who manufactured or assembled the product; or".";

(b) after paragraph (3) insert—

"(4) At the end insert—

"(6) Regulation 18 does not apply to a person ("P") who imports a medicinal product into Great Britain from an approved country for import for administration to P or to any other person who is a member of P's household.".".

12. In regulation 18 (amendment of Schedule 3 (applications for licences under Part 3))—

(a) for paragraph (2) substitute—

"(2) For paragraph 1(2)(g) substitute—

"(g) the name, address, qualifications and experience of the person with responsibility for quality control in relation to the medicinal products to be manufactured or assembled under the licence (and, if that responsibility is to be carried out by the holder of—

(i) in the case of a product for sale or supply in Great Britain, the UK marketing authorisation, certificate of registration or traditional herbal registration relating to the products, or

(ii) in the case of a product for sale or supply in Northern Ireland, the marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration relating to the products,

a statement of that fact);".";

(b) for paragraph (3) substitute—

"(3) For paragraph 2(1) substitute—

"**2.**—(1) This paragraph applies to an application for a manufacturer's licence relating to the import from—

(a) in the case of an import into Great Britain, a country other than Northern Ireland or a country other than an approved country for import, or

(b) in the case of an import into Northern Ireland, a country other than an EEA State,

of medicinal products.".";

(c) in paragraph (4)(b)—

(i) for sub-paragraph (i) substitute—

"(i) for paragraph (i) substitute—

"(i) in the case of a product for sale or supply in Great Britain, a UK marketing authorisation,

(ia) in the case of a product for sale or supply in Northern Ireland, a marketing authorisation,",";

(ii) for sub-paragraph (ii) substitute—

"(ii) in paragraph (iv) before "an Article" insert "in the case of a product for sale or supply in Northern Ireland,", and";

(d) in paragraph (4)(c)(iii), in the inserted paragraph (iii), after "export" insert "from Great Britain".

13. After regulation 19 (amendment of regulation 23 (grant or refusal of licence)) insert—

"**Amendment of regulation 24 (standard provisions of licences)**

19A. In regulation 24, after paragraph (2) insert—

"(3) In Schedule 4, in relation to a licence holder in Great Britain, references to the principles and guidelines set out in the Good Manufacturing Practice Directive are to those principles and guidelines as they apply under or by virtue of regulation B17.".".

14. In regulation 20 (amendment of Schedule 4 (standard provisions of licences under Part 3))—

(a) for paragraph (2) substitute—

"(2) For paragraph 13(b) substitute—

"(b) in the case of a product for sale or supply—

(i) in Great Britain, a UK marketing authorisation, certificate of registration or traditional herbal registration, or

(ii) in Northern Ireland, a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration,

contains provisions relating to them,".";

(b) after paragraph (2) insert—

"(2A) After paragraph 14 insert—

"**14A.** A licence holder—

(a) in Great Britain may only supply a special medicinal product to a person in Northern Ireland, and

(b) in Northern Ireland may only supply a special medicinal product to a person in Great Britain,

in response to an order which satisfies the requirements of regulation 167.".";

(c) for paragraph (3) substitute—

"(3) In the heading of Part 2, after "State Other Than an EEA State" insert "/ Country other than an Approved Country for Import".";

(d) for paragraph (4) substitute—

"(4) In paragraph 15, for "from a state other than an EEA State" substitute—

"from—

(a) in the case of an import into Great Britain, a country other than Northern Ireland or a country other than an approved country for import, or

(b) in the case of an import into Northern Ireland, a country other than an EEA State".

(4A) In paragraphs 22(1) and 23, for "a state other than an EEA State" substitute ", in the case of an import into Great Britain, a country other than Northern Ireland or a country other than an approved country for import and in the case of an import into Northern Ireland, a country other than an EEA State".

(4B) After paragraph 23, insert—

"**23A.** A licence holder—

(a) in Great Britain may only supply a special medicinal product to a person in Northern Ireland, and

(b) in Northern Ireland may only supply a special medicinal product to a person in Great Britain,

in response to an order which satisfies the requirements of regulation 167.".";

(e) for paragraph (6) substitute—

"(6) In paragraph 33, for "another EEA State" substitute ", in the case of an import into Great Britain, an approved country for import and in the case of an import into Northern Ireland, an EEA State".";

(f) after paragraph (6) insert—

"(7) After paragraph 41 insert—

"**41A.** A licence holder—

(a) in Great Britain may only supply a special medicinal product to a person in Northern Ireland, and

(b) in Northern Ireland may only supply a special medicinal product to a person in Great Britain,

in response to an order which satisfies the requirements of regulation 167.".".

15. For regulation 21 (amendment of regulation 26 (general power to suspend, revoke or vary licences)) substitute—

"**21.** For regulation 26(5)(a) substitute—

"(a) that the holder of the manufacturer's licence has manufactured or assembled medicinal products to the order of a person who holds—

(i) in the case of a product for sale or supply in Great Britain, a UKMA(GB), a UKMA(UK), a COR(GB), a COR(UK), a THR(GB) or a THR(UK) (an "authorisation"), or

(ii) in the case of a product for sale or supply in Northern Ireland, a UKMA(NI), a UKMA(UK), a COR(NI), a COR(UK), a THR(NI) or a THR(UK), an EU marketing authorisation or an Article 126a authorisation (an "authorisation"),

and has habitually failed to comply with the provisions of that authorisation; or".".

16. In regulation 24 (amendment of regulation 31 (certification of manufacturer's licence)) for paragraph (3) substitute—

"(3) In paragraphs (3)(b), (5)(a) and (5)(b) for "marketing authorisation" substitute "UK marketing authorisation, EU marketing authorisation, Article 126a authorisation".".

17. In regulation 27 (amendment of regulation 36 (conditions for manufacturer's licence)) for ", omit paragraphs (4) to (7)" substitute—

"—

(a) in paragraph (4)—

(i) for "The requirements" substitute "Where a manufacturer's licence relates to the manufacture or assembly of a medicinal product in, or import of a medicinal product into, Northern Ireland, the requirements";

(ii) for "provisions of a manufacturer's" substitute "provisions of that";

(b) in paragraph (6), after "by way of wholesale dealing" insert "in Northern Ireland".".

18. In regulation 28 (amendment of regulation 37 (manufacturing and assembly))—

(a) after paragraph (1) insert—

"(1A) In paragraph (2), after "Good Manufacturing Practice Directive" insert "which apply under or by virtue of regulation B17".".

(b) for paragraph (2) substitute—

"(2) For paragraph (4)(b) substitute—

"(b) that unless the active substance is imported into Great Britain from a country other than an approved country for import or into Northern Ireland from a country other than an EEA State from a third country, any manufacturers, importers or distributors supplying active substances to the licence holder—

(i) in the case of a product imported into Great Britain, are registered with the appropriate authority for the registration of such persons in the approved country for import, and

(ii) in the case of a product imported into Northern Ireland, are registered with the competent authority of a member State in which they are established; and".";

(c) for paragraph (3) substitute—

"(3) In paragraph (5)(b), after "as described" insert "in the case of a product for sale or supply in Great Britain, in the guidelines which apply under or by virtue of regulation C17 and, in the case of a product for sale or supply in Northern Ireland,";

(d) for paragraph (4) substitute—

"(4) For paragraph (6)(b) substitute—

"(b) in the case of a product for sale or supply—

(i) in Great Britain, the UKMA(GB), UKMA(UK), COR(GB), COR(UK), THR(GB) or THR(UK), or

(ii) in Northern Ireland, the UKMA(NI), UKMA(UK), COR(NI), COR(UK), THR(NI), THR(UK), EU marketing authorisations or Article 126a authorisations,

applying to the medicinal products.".".

19. In regulation 29 (amendment of regulation 38 (imports))—

(a) for paragraph (2) substitute—

"(2) In the heading, after "states other than EEA states" insert "/ countries other than approved countries for import".";

(b) for paragraph (3) substitute—

"(3) In paragraph (2) for "from a state other than an EEA State" substitute—

"from—

(a) in the case of an import into Great Britain, a country other than an approved country for import, or

(b) in the case of an import into Northern Ireland, a country other than an EEA State".";

(c) after paragraph (3) insert—

"(4) In paragraph (3)(b) for "a state other than an EEA State" substitute ", in the case of an import into Great Britain, a country other than an approved country for import and in the case of an import into Northern Ireland, a country other than an EEA State".".

20. In regulation 30 (amendment of regulation 39 (further requirements for manufacturer's licence))—

(a) "omit ", 43A"" becomes paragraph (a);

(b) after paragraph (a) insert—

"and

(b) after "and (6)" insert "and, where the product is being distributed in Northern Ireland, regulation 43A,".".

21. In regulation 31 (amendment of regulation 42 (conditions for wholesale dealer's licence))—

(a) for paragraph (2) substitute—

"(2) In paragraph (1), after "45" insert "(in the case of a wholesale dealer's licence held in Northern Ireland) or regulations 43 to 45AA (in the case of a wholesale dealer's licence held in Great Britain)".";

(b) for paragraph (3) substitute—

"(3) In paragraph (4)—

(a) for "The requirements" substitute "Where a wholesale dealer's licence relates to wholesale dealings in Northern Ireland, the requirements"; and

(b) for "provisions of a wholesale dealer's" substitute "provisions of that".".

22. In regulation 32 (amendment of Schedule 7 (qualified persons))—

(a) after paragraph (3)(a)(i) insert—

"(ia) for "The qualified person" substitute "In Great Britain, the qualified person";";

(b) in paragraph (3)(a)(ii), before sub-paragraph (aa), insert—

"(zaa) for "the United Kingdom" substitute "Great Britain";";

(c) in paragraph (3)(a)(iii)(aa) after "medicinal products imported from" insert "a country other than Northern Ireland or";

(d) after paragraph (3)(a) insert—

"(aa) after paragraph 12 insert—

"**12A.**—(1) In Northern Ireland, the qualified person is responsible for securing—

(a) that each batch of medicinal products manufactured in Northern Ireland has been manufactured and checked in accordance with these Regulations and the requirements of the marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration relating to those products; and

(b) in the case of medicinal products imported from a country other than an EEA State, irrespective of whether the products have been manufactured in Northern Ireland or an EEA State, that each batch has undergone—

(i) a full qualitative analysis,

(ii) a quantitative analysis of all the active substances, and

(iii) all other tests or checks necessary to ensure the quality of medicinal products in accordance with the requirements of the marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration relating to those products; and

(c) in the case of medicinal products, other than radiopharmaceuticals, that are required to bear safety features pursuant to Article 54a of the 2001 Directive and not intended to be exported to a country other than an EEA State, that the features specified in paragraph 18A of Schedule 24 have been affixed on the packaging.".";

(e) for paragraph (3)(b) substitute—

"(b) in paragraph 13—

(i) in sub-paragraph (1) after "This paragraph applies" insert "in Northern Ireland";

(ii) in sub-paragraph (1)(a) for "paragraph 12 in another member State is imported to the United Kingdom" substitute "paragraph 12A in a member State is imported to Northern Ireland";

(iii) in sub-paragraph (2) for "12" substitute "12A";";

(f) in paragraph (3)(c)—

(i) for paragraph (i) substitute—

"(i) in sub-paragraph (1)(a) after "are imported" insert "into Great Britain from a country other than an approved country for import or into Northern Ireland;";

(ii) for paragraph (ii) substitute—

"(ii) for sub-paragraph (1)(b) substitute—

"(b) appropriate arrangements have been made, in the case of import into Great Britain by the licensing authority with the country from which those products are imported and, in the case of a product for import into Northern Ireland by the European Union with that country, to ensure that—

(i) the manufacturer of the medicinal products applies standards of good manufacturing practice at least equivalent to those laid down—

(aa) in the case of a product for sale or supply in Great Britain, in the Good Manufacturing Practice Directive, as supplemented by the guidelines and principles which apply under, or by virtue of, regulation C17, and

(bb) in the case of a product for sale or supply in Northern Ireland, by the European Union;

(ii) the controls referred to in paragraph 12(b) or 12A(b) (as appropriate) have been carried out in that country.".";

(iii) after paragraph (ii) insert—

"(iia) in paragraph (2) after "paragraph 12" insert "or 12A".".

23. In regulation 33 (amendment of regulation 43 (obligations of licence holder))—

(a) for paragraph (2) substitute—

"(2) For paragraph (1), substitute—

"**43.**—(1) The licence holder must comply with the guidelines on good distribution practice—

(a) in the case of a licence holder in Great Britain, published under, or that apply by virtue of, regulation C17;

(b) in the case of a licence holder in Northern Ireland, published by the European Commission in accordance with Article 84 of the 2001 Directive.".";

(b) for paragraph (3) substitute—

"(3) For paragraph (5)(a) substitute—

"(a) in the case of a product for sale or supply—

(i) in Great Britain, there is a UKMA(GB), UKMA(UK), a COR(GB), a COR(UK), a THR(GB) or a THR(UK) (an "authorisation"), or

(ii) in Northern Ireland, there is a UKMA(NI), UKMA(UK), a COR(NI), a COR(UK), a THR(NI), a THR(UK), and EU marketing authorisation or an Article 126a authorisation (an "authorisation"),

in force in relation to the product; and".";

(c) after paragraph (4)(a) insert—

"(aa) in sub-paragraph (b), after "the export" insert "from Northern Ireland";";

(d) in paragraph (4)(b)—

(i) for "for sub-paragraph (b), substitute" substitute "after sub-paragraph (b), insert";

(ii) in the text inserted by that paragraph—

(aa) renumber the paragraph to be inserted as "(ba)";

(bb) after "the export" insert "from Great Britain";

(e) after paragraph (4)(b) insert—

"(c) for sub-paragraph (d) substitute—

"(d) the wholesale distribution of medicinal products—

(i) from Northern Ireland to a person in a country other than Great Britain or a country other than an EEA State; or

(ii) from Great Britain to a person in a country other than Northern Ireland or a country other than an approved country for import.".";

(f) in paragraph (5)(a)—

(i) for paragraph (i) substitute—

"(i) for sub-paragraph (i) substitute—

"(i) ordered by the licensing authority or—

(aa) in the case of a licence holder in Great Britain, by an appropriate authority for the licensing of medicinal products in an approved country for import;

(bb) in the case of a licence holder in Northern Ireland, by the competent authority of any EEA State, or";";

(ii) for paragraph (ii) substitute—

"(ii) for sub-paragraph (ii) substitute—

"(ii) carried out in co-operation with the manufacturer of, or the holder of—

(aa) in the case of a product for sale or supply in Great Britain, the UKMA(GB) or UKMA(UK), certificate of registration or traditional herbal registration, or

(bb) in the case of a product for sale or supply in Northern Ireland, the UKMA(NI) or UKMA(UK), EU marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration,

for, the product; and";";

(g) for paragraph (5)(b) substitute—

"(b) in sub-paragraph (c)(vii), before "the batch number" insert "where the receipt, dispatch or brokering of medicinal products takes places in Northern Ireland,";";

(h) after paragraph (5) insert—

"(5A) In paragraph (8)—

(a) after "A licence holder" insert "in Northern Ireland";

(b) for "third country" substitute ""country other than an EEA State".";

(i) in paragraph (6)—

(i) for "For paragraph (8) substitute" substitute "After paragraph (8) insert";

(ii) renumber the paragraphs to be inserted as (8A) and (8B) respectively;

(iii) in the newly renumbered paragraph (8A)—

(aa) for "Paragraph (8A)" substitute "Paragraph (8B)";

(bb) in sub-paragraph (a), after "imports" insert "into Great Britain";

(j) for paragraph (7) substitute—

"(7) In paragraph (10), after "The holder" insert "of a licence relating to wholesale dealings in Northern Ireland".";

(k) for paragraph (8) substitute—

"(8) In paragraph (13), for "marketing authorisation holder" substitute "UK marketing authorisation holder or EU marketing authorisation holder".";

(l) for paragraph (9) substitute—

"(9) For paragraph (14) substitute—

"(14) Where the medicinal product is obtained through brokering—

(a) a licence holder in Great Britain must verify that the broker involved fulfils the requirements set out in regulation 45A(1)(b);

(b) a licence holder in Northern Ireland must verify that the broker involved is validly registered with the licensing authority or the competent authority of an EEA State.".

(10) In paragraph (15), after "In this regulation" insert "as it applies in the case of a product for sale or supply in Northern Ireland".".

24. For regulation 34 (omission of regulation 43A (requirement for wholesale dealers to decommission the unique identifier)) substitute—

"**Amendment of regulation 43A (requirement for wholesale dealers to decommission the unique identifier)**

34. In regulation 43A—

(a) in paragraph (2) for "in the United Kingdom" substitute "in Northern Ireland"; and

(b) in paragraph (3)—

(i) in sub-paragraph (g) omit "a police force in England, Wales or Scotland or"; and

(ii) in sub-paragraph (l) for "care" substitute "nursing".".

25. In regulation 35 (amendment of regulation 44 (requirement for wholesale dealers to deal only with specified persons))—

(a) in paragraph (2)—

(i) for sub-paragraph (a) substitute—

"(a) in sub-paragraph (b), for "another EEA State" substitute "an approved country for import (in the case of a licence holder in Great Britain) or by an EEA State (in the case of a licence holder in Northern Ireland)"; and";

(ii) for sub-paragraph (b) substitute—

"(b) for sub-paragraph (c) substitute—

"(c) where the medicinal product is directly received—

(i) in the case of a licence holder in Great Britain, from a country that is not an approved country for import ("A"), for export to a country that is not an approved country for import ("B"), and

(ii) in the case of a licence holder in Northern Ireland, from a country other than an EEA State ("A") for export to another country other than an EEA State ("B") ,

the supplier of the medicinal product in country A is a person who is authorised or entitled to supply such medicinal products in accordance with the legal and administrative provisions in country A.".";

(b) for paragraph (3) substitute—

"(3) For paragraph (5)(b) substitute—

"(b) the holder of an authorisation granted by—

(i) in the case of a licence holder in Great Britain, the appropriate authority of an approved country for import;

(ii) in the case of a licence holder in Northern Ireland, the competent authority of an EEA State,

that is responsible for authorising the supply of those products by way of wholesale dealing;".";

(c) for paragraph (4) substitute—

"(4) For paragraph (5)(e) substitute—

"(e) in relation to supply—

(i) in the case of a licence holder in Great Britain to persons in countries other than approved countries for import, a person who is authorised or entitled to receive medicinal products for wholesale distribution or supply to the public in accordance with the applicable legal and administrative provisions of the country to which the product is supplied;

(ii) in the case of a licence holder in Northern Ireland to persons in a country other than an EEA State, a person who is authorised or entitled to receive medicinal products for wholesale distribution or supply to the public in accordance with the applicable legal and administrative provisions of the country other than an EEA State concerned.".";

(d) for paragraph (5)(b) substitute—

"(b) in sub-paragraph (e) after "of the 2001 Directive" insert ", in the case of a licence holder in Northern Ireland.".";

(e) after paragraph (5) insert—

"(6) After paragraph (7) insert—

"(8) A licence holder in Great Britain may only obtain a medicinal product in respect of which a UKMA(GB) was granted under the unfettered access route if the product satisfies the definition of qualifying Northern Ireland goods.

(9) Paragraph (2)(c) does not apply to—

(a) in the case of a licence holder in Great Britain, products received from Northern Ireland, and

(b) in the case of a licence holder in Northern Ireland, products received from Great Britain.

(10) Paragraph (5)(e) does not apply to—

(a) in the case of a licence holder in Great Britain, products supplied to Northern Ireland, and

(b) in the case of a licence holder in Northern Ireland, products supplied to Great Britain.".".

26. In regulation 36 (amendment of regulation 45 (requirement as to responsible persons))—

(a) for paragraph (2) substitute—

"(2) After paragraph (1) insert—

"(1A) In respect of a licence holder in Great Britain, paragraph (1) is subject to regulation 45AA.".";

(b) for paragraph (3) substitute—

"(3) For paragraph (2)(b) substitute—

"(b) ensuring that the quality of medicinal products handled by the licence holder is being maintained in accordance with the requirements of—

(i) in the case of a licence holder in Great Britain, the UK marketing authorisations, certificates of registration or traditional herbal registrations, and

(ii) in the case of a licence holder in Northern Ireland, the marketing authorisations, Article 126a authorisations, certificates of registration or traditional herbal registrations,

applicable to those products.".".

27. In regulation 37 (insertion of new regulations 45AA and 45AB (responsible persons: import)), in the inserted regulation 45AA—

(a) in paragraph (1), after "this regulation applies" insert "to a licence holder in Great Britain";

(b) omit "and" at the end of paragraph (4)(a);

(c) at the end of paragraph (4)(b) insert—

"; and

(c) ensure that each production batch of a medicinal product that is subject to the batch testing condition and that is imported into Great Britain from an approved country for import has been certified as being in conformity with the approved specifications in the UK marketing authorisation by—

(i) the appropriate authority, or

(ii) where the batch testing exemption applies, a laboratory in a country that has an agreement with the United Kingdom to the effect that the appropriate authority will recognise that certificate in place of the appropriate authority's own examination.".

28. In regulation 38 (amendment of regulation 45A (brokering in medicinal products))—

(a) for paragraph (2) substitute—

"(2) For paragraph (1) substitute—

"(1) A person may not broker a medicinal product in Great Britain unless—

(a) the product is covered by an authorisation granted—

(i) by the licensing authority, or

(ii) by an appropriate authority responsible for the licensing of medicinal products in an approved country for import, and

(b) that person—

(i) is validly registered as a broker with the licensing authority,

(ii) has a permanent address in the United Kingdom, and

(iii) complies with the guidelines on good distribution practice which apply under, or by virtue of, regulation C17 insofar as those guidelines apply to brokers.

(1A) A person may not broker a medicinal product in Northern Ireland unless—

(a) the product is covered by an authorisation granted—

(i) under Regulation (EC) No 726/2004,

(ii) by the licensing authority, or

(iii) by a competent authority of a member State, and

(b) that person—

(i) is validly registered as a broker with the licensing authority or a competent authority of a member State,

(ii) except where the person is validly registered with the competent authority of an EEA State, has a permanent address in the United Kingdom, and

(iii) complies with the guidelines on good distribution practice published by the European Commission in accordance with Article 84 of the 2001 Directive insofar as those guidelines apply to brokers.”.”;

(b) for paragraph (3) substitute—

“(3) In paragraph (2)—

(a) after “paragraph (1)(b)” insert “or (1A)(b)”;

(b) in sub-paragraphs (a) and (c), after “competent authority of a member State” insert “or the licensing authority (as appropriate)”.”.

29. In regulation 40 (amendment of regulation 45E (criteria of broker’s registration))—

(a) for paragraph (a) substitute—

“(a) for sub-paragraph (b)(i) substitute—

“(i) ordered by—

(aa) in the case of a broker in Great Britain, the licensing authority or by an appropriate authority responsible for the licensing of medicinal products in an approved country for import, or

(bb) in the case of a broker in Northern Ireland, the licensing authority or by the competent authority of any EEA State, or”;”;

(b) for paragraph (b) substitute—

“(b) in sub-paragraph (d)(iii), before “the batch number” insert “where the sale or supply of the medicinal product is in Northern Ireland,”.”.

30. In regulation 41 (amendment of regulation 45F (provision of information)), for the inserted sub-paragraph (b) substitute—

“(b) in the case of a broker in—

(i) Great Britain, either—

(aa) the UK marketing authorisation holder, or

(bb) where applicable, the holder of the licence or authorisation granted by an appropriate authority responsible for the licensing of medicinal products in an approved country for import, or

(ii) Northern Ireland, either—

(aa) the UK marketing authorisation holder, or

(bb) where applicable, the EU marketing authorisation holder,".

31. In regulation 42 (amendment of regulation 45M (criteria for importation, manufacture or distribution of an active substance)) for paragraph (2) substitute—

"(2) For paragraph (2)(a) substitute—

"(a) if—

(i) in the case of a product for sale or supply in Great Britain, the product has a UK marketing authorisation, certificate of registration or traditional herbal registration, or

(ii) in the case of a product for sale or supply in Northern Ireland, the product has a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration, and";".

32. In regulation 44 (amendment of regulation 45O (requirements for registration as an importer, manufacturer or distributor of an active substance))—

(a) for paragraph (2) substitute—

"(2) For paragraph (1) substitute—

"(1) Where principles and guidelines of good manufacturing practice have been published under, or apply by virtue of, regulation C17, which apply to an active substance manufactured in Great Britain, a manufacturer in Great Britain must comply with the principles and guidelines of good manufacturing practice for active substances.

(1A) Where the Commission has adopted principles and guidelines of good manufacturing practice under the third paragraph of Article 47 of the 2001 Directive which applies to an active substance manufactured in Northern Ireland, a manufacturer in Northern Ireland must comply with the principles and guidelines of good manufacturing practice for active substances.".";

(b) for paragraph (3) substitute—

"(3) For paragraph (2) substitute—

"(2) Where principles and guidelines of good distribution practice have been published under, or apply by virtue of, regulation C17, which apply to an active substance distributed in Great Britain, a distributor in Great Britain must comply with the principles and guidelines of good distribution practice for active substances.

(2A) Where the Commission has adopted principles and guidelines of good distribution practice under the fourth paragraph of Article 47 of the 2001 Directive which applies to an active substance distributed in the Northern Ireland, a distributor in Northern Ireland must comply with the principles and guidelines of good distribution practice for active substances.".";

(c) for paragraph (4) substitute—

"(4) In paragraph (3)—

(a) for "the UK" substitute "Northern Ireland";

(b) for "from a third country" substitute "into Northern Ireland from a country other than an EEA State";

(c) for "exporting third country" in both places it occurs substitute "exporting country";

(d) in sub-paragraph (c)(ii), for "the Union" substitute "Northern Ireland".";

(d) after paragraph (4) insert—

"(4A) After paragraph (3) insert—

"(3A) Without prejudice to regulation 37(4) and paragraph 9A of Schedule 8, where principles and guidelines of good manufacturing practice have been published under, or apply by virtue of, regulation C17, which apply to an active substance imported into Great Britain other than from Northern Ireland and where an active substance is so imported—

(a) the importer must comply with good manufacturing practice and good distribution practice in relation to the active substance,

(b) the active substances must have been manufactured in accordance with standards which are at least equivalent to good manufacturing practice, and

(c) the active substances must be accompanied by a written confirmation from the competent authority of the exporting country of the following—

(i) the standards of manufacturing practice applicable to the plant manufacturing the exported active substance are at least equivalent to good manufacturing practice,

(ii) the manufacturing plant concerned is subject to regular, strict and transparent controls and to the effective enforcement of standards of manufacturing practice at least equivalent to good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in Great Britain, and

(iii) in the event of findings relating to non-compliance, information on such findings is supplied by the exporting country to the licensing authority without any delay.".";

(e) for paragraph (5) substitute—

"(5) In paragraph (4)—

(a) for "(3)(c) does" substitute "(3)(c) and (3A)(c) do";

(b) in sub-paragraph (a), after "Article 111b of the 2001 Directive" insert "(in the case of an import into Northern Ireland) or paragraph (6) (in the case of an import into Great Britain)";

(c) in sub-paragraph (b)(i), after "competent authority of a member State" insert "or licensing authority (in the case of an import into Northern Ireland) or licensing authority or an appropriate authority responsible for the licensing of medicinal products in a country included in a list under paragraph (6) (in the case of an import into Great Britain)".";

(f) in paragraph (6), in the inserted paragraph (6), for "the United Kingdom" in both places substitute "Great Britain".