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STATUTORY INSTRUMENTS

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**2013 No. 1855**

**MEDICINES**

**The Human Medicines (Amendment) Regulations 2013**

*Made* - - - - *22nd July 2013*

*Laid before Parliament* *29th July 2013*

*Coming into force in accordance with regulation 1*

The Secretary of State and the Minister for Health, Social Services and Public Safety make the following Regulations. They do so in the exercise of the powers conferred by—

- section 2(2) and (5) of the European Communities Act 1972(1), having been designated for the purposes of section 2(2) of that Act in relation to medicinal products(2);
- section 58(1), (4), (4A) and (5) of the Medicines Act 1968(3);
- section 1(1) and (2) of the Medicines Act 1971(4) or, in the case of the Minister, the powers conferred by those provisions and now vested in him(5).

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- (1) [1972 c.68](#). Section 2(2) was amended by section 27(1)(a) of the Legislative Reform Act 2006 ([2006 c.51](#)) and section 3(3) of and Part 1 of the Schedule to the European Union (Amendment) Act 2008 ([2008 c.7](#)). Section 2(5) was amended by section 41(1) of and Part 1 of Schedule 6 to the Northern Ireland Constitution Act 1973 ([1973 c.36](#)).
- (2) *See* [S.I. 1972/1811](#) regarding the designation of Ministers.
- (3) [1968 c.67](#). Relevant amendments to section 58(1) have been made by [S.I. 2006/2407](#) and [2012/1916](#). Relevant amendments to section 58(4) have been made by the Medicinal Products: Prescription by Nurses etc. Act 1992 ([c.28](#)) and [S.I. 2006/2407](#) and [2012/1916](#). Section 58(4A) has been amended by [S.I. 2012/1916](#). Relevant amendments to section 58(5) have been made by the Medicinal Products: Prescription by Nurses etc. Act 1992 and the Health and Social Care Act 2001 ([c.15](#)).
- (4) [1971 c.69](#); as amended by regulation 45(2) of [S.I. 2008/2297](#) and section 21 of the Health and Medicines Act 1988 ([c.49](#)). By virtue of section 1(3) of the Medicines Act 1971 (“the 1971 Act”), expressions used in that section have the same meaning as in the Medicines Act [1968 \(c.67\)](#) (“the 1968 Act”). *See* therefore section 1 of the 1968 Act, as substituted by paragraph 2 of Schedule 34 to the Human Medicines Regulations 2012 ([S.I. 2012/1916](#)) (“the 2012 Regulations”) which provides the meaning of the expression “the Ministers”, which is relevant to the powers being exercised in the making of these Regulations. By virtue of regulation 348 of, and paragraph 36 of Schedule 34 to, the 2012 Regulations, references in section 1(1) and (2) (b) of the 1971 Act to an application for a licence, or for the variation or renewal of such a licence under Part 2 of the 1968 Act, shall have effect as a reference to any application under Parts 3 to 8 of the 2012 Regulations.
- (5) In the case of the Secretary of State, by virtue of article 2(1) of [S.I. 1999/3142](#). In the case of the Minister for Health, Social Services and Public Safety, by virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 ([c.47](#)); the Department for which the Minister is responsible was renamed by virtue of Article 3(6) of [S.I. 1999/283 \(N.I.1\)](#).

## PART 1

### Introduction

#### Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Human Medicines (Amendment) Regulations 2013 and subject to paragraph (2) shall come into force on 20th August 2013.

(2) Regulation 28 shall come into force one year after the date of publication in the Official Journal of the European Union of the implementing acts referred to in Article 85c(3) (provisions as to the sale at a distance of medicinal products) of Directive [2001/83/EC](#) of the European Parliament and of the Council on the Community code relating to medicinal products for human use<sup>(6)</sup>.

(3) Regulation 31 shall come into force immediately after regulations 32 to 35.

## PART 2

### Amendment of the Human Medicines Regulations 2012

#### Part 2: General

2. The Human Medicines Regulations 2012<sup>(7)</sup> are amended in accordance with this Part.

#### Amendment of regulation 8

3. In regulation 8 (general interpretation)—

(a) in paragraph (1)—

(i) after the definition of “the 2001 Directive” insert—

““active substance” means any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis;”;

(ii) for the definition of “assemble” substitute—

““assemble”, in relation to a medicinal product or an active substance, includes the various processes of dividing up, packaging and presentation of the product or substance, and “assembly” has a corresponding meaning;”;

(iii) after the definition of “the British Pharmacopoeia” insert—

““brokering” means all activities in relation to the sale or purchase of medicinal products, except for wholesale distribution, that do not include physical handling and that consist of negotiating independently and on behalf of another legal or natural person;”;

(iv) after the definition of “the European Pharmacopoeia” insert—

““excipient” means any constituent of a medicinal product other than the active substance and the packaging material;”;

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(6) OJ No L 311, 28.11.2001, p67. Article 85c was inserted into Directive [2001/83/EC](#) by Article 1(2) of Directive 2011/62/EU of the European Parliament and of the Council (OJ No L 174, 1.7.2011, p74).

(7) [S.I. 2012/1916](#).

- (v) for the definition of “export” substitute—  
““export” means export, or attempt to export, from the United Kingdom, whether by land, sea or air;”;
- (vi) before the definition of “the Good Manufacturing Practice Directive” insert—  
““falsified medicinal product” means any medicinal product with a false representation of—  
(a) its identity, including its packaging and labelling, its name or its composition (other than any unintentional quality defect) as regards any of its ingredients including excipients and the strength of those ingredients;  
(b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or  
(c) its history, including the records and documents relating to the distribution channels used;  
“Fees Regulations” means the Medicines (Products for Human Use) (Fees) Regulations 2013(8);”;
- (vii) after the definition of “immediate packaging” insert—  
““import” means import, or attempt to import, into the United Kingdom, whether by land, sea or air;”;
- (viii) after the definition of “pharmacy medicine”, insert—  
““physiotherapist independent prescriber” means a person—  
(a) who is a registered physiotherapist; and  
(b) against whose name is recorded in the relevant register an annotation signifying that the person is qualified to order drugs, medicines and appliances as a physiotherapist independent prescriber;  
“podiatrist independent prescriber” means a person—  
(a) who is a registered podiatrist; and  
(b) against whose name is recorded in the relevant register an annotation signifying that the person is qualified to order drugs, medicines and appliances as a podiatrist independent prescriber;”;
- (b) after paragraph (7), insert—  
“(8) References in these Regulations to—  
(a) good manufacturing practice for active substances relate to the principles and guidelines for good manufacturing practice adopted by the European Commission under the third paragraph of Article 47(9) of the 2001 Directive;  
(b) good distribution practice for active substances relate to the guidelines on good distribution practices for active substances adopted by the European Commission under the fourth paragraph of Article 47 of the 2001 Directive.”

### **Insertion of regulation A17**

4. In Part 3, before the heading “Manufacturing and wholesale dealing” there is inserted—

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(8) [S.I. 2013/532](#).

(9) Paragraphs 3 and 4 of Article 47 were substituted by Directive 2011/62/EU of the European Parliament and of the Council (OJ No L 174, 1.7.2011, p74).

*“Manufacture and distribution of medicinal products and active substances*

CHAPTER 1

Interpretation

**Interpretation**

**A17.** In this Part “manufacture”, in relation to an active substance, includes any process carried out in the course of making the substance and the various processes of dividing up, packaging, and presentation of the active substance.  
CHAPTER 2”.

**Substitution of regulation 18**

5. For regulation 18 (wholesale dealing in medicinal products) substitute—

**“Wholesale dealing in medicinal products**

**18.**—(1) A person may not except in accordance with a licence (a “wholesale dealer’s licence”)—

- (a) distribute a medicinal product by way of wholesale dealing; or
- (b) possess a medicinal product for the purpose of such distribution.

(2) Paragraph (1)—

- (a) does not apply—
  - (i) to anything done in relation to a medicinal product by the holder of a manufacturer’s licence in respect of that product,
  - (ii) where the product concerned is an investigational medicinal product, or
  - (iii) if the product is a radiopharmaceutical in which the radionuclide is in the form of a sealed source; and
- (b) is subject to regulation 19.

(3) Distribution of a medicinal product by way of wholesale dealing, or possession for the purpose of such distribution, is not to be taken to be in accordance with a wholesale dealer’s licence unless the distribution is carried on, or as the case may be the product held, at premises located in the UK and specified in the licence.

(4) In these Regulations a reference to distributing a product by way of wholesale dealing is a reference to—

- (a) selling or supplying it; or
- (b) procuring or holding it or exporting it for the purposes of sale or supply,

to a person who receives it for a purpose within paragraph (5).

(5) Those purposes are—

- (a) selling or supplying the product; or
- (b) administering it or causing it to be administered to one or more human beings,

in the course of a business carried on by that person.

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

unless a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration is in force in respect of the product but this—

- (a) does not apply in relation to distribution by a person to a person in a third country; and
  - (b) is subject to the exceptions in regulation 43(6).
- (7) In paragraph (6), “marketing authorisation” means—
- (a) a marketing authorisation issued by a competent authority of a member State in accordance with the 2001 Directive; or
  - (b) an EU marketing authorisation.”

#### **Amendment of regulation 19**

6. In regulation 19 (exemptions from requirement for wholesale dealers licence) omit paragraph (5).

#### **Amendment of regulation 20**

7. In regulation 20(1) (mixing of medicines)—
- (a) after sub-paragraph (c) insert—
    - “(ca) physiotherapist independent prescriber;
    - (cb) podiatrist independent prescriber;”;
  - (b) in sub-paragraph (d)(iii) omit “or”;
  - (c) for sub-paragraph (d)(iv) substitute—
    - “(iv) pharmacist independent prescriber,
    - (v) physiotherapist independent prescriber, or
    - (vi) podiatrist independent prescriber; or”.

#### **Amendment of regulation 27**

8. In regulation 27 (procedure where licensing authority proposes to suspend, revoke or vary licence), for paragraph (5) substitute—

- “(5) If the licence holder notifies the licensing authority that the holder wishes the licensing authority to submit the proposal to review upon oral representations in accordance with paragraph (3)(b)—
- (a) Schedule 5 has effect; and
  - (b) the licence holder must pay a fee for a review upon oral representations in accordance with the Fees Regulations.”

#### **Amendment of regulation 34**

9. In regulation 34 (offences: breach of regulations and false information and defence concerning starting materials)—

- (a) in paragraph (1), for “, 18(1) or 32” substitute “or 18(1)”; and
- (b) in paragraphs (4) and (5), for “37(2)(b)” substitute “37(3)” .

### Amendment of regulation 36

10. In regulation 36 (conditions for manufacturer's licence), in paragraph (2) for "37(2)(b)" substitute "37(3)".

### Substitution of regulation 37

11. For regulation 37 (manufacturing and assembly) substitute—

#### **"Manufacturing and assembly**

37.—(1) This regulation applies in relation to a manufacturer's licence relating to the manufacture or assembly of medicinal products.

(2) The licence holder must comply with the principles and guidelines for good manufacturing practice set out in the Good Manufacturing Practice Directive.

(3) Unless paragraph (10) applies, the licence holder shall use active substances as starting materials only if—

- (a) those substances have been manufactured in accordance with good manufacturing practice for active substances; and
- (b) those substances have been distributed in accordance with the guidelines on good distribution practice for active substances.

(4) The licence holder shall verify—

- (a) that the manufacturer or distributor of an active substance used by the licence holder has complied with the requirements of good manufacturing practice and good distribution practice for active substances by means of audits performed—
  - (i) directly by the licence holder, or
  - (ii) by a person acting on behalf of the licence holder under a contract;
- (b) that unless the active substance is imported from a third country, any manufacturers, importers or distributors supplying active substances to the licence holder are registered with the competent authority of a member State in which they are established; and
- (c) the authenticity and quality of the active substance.

(5) The licence holder shall ensure that—

- (a) excipients are suitable for use in a medicinal product by—
  - (i) ascertaining what the appropriate good manufacturing practice is, and
  - (ii) ensuring that the ascertained good manufacturing practice is applied;
- (b) the suitability of the excipient is ascertained on the basis of a formalised risk assessment as described in paragraph 5 of Article 47(10) of the 2001 Directive;
- (c) the assessment under sub-paragraph (b) takes account of—
  - (i) the source,
  - (ii) requirements under other quality systems,
  - (iii) intended use of the excipients, and
  - (iv) previous instances of quality defects,
- (d) the authenticity and quality of any excipient used is verified; and

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(10) Paragraph 5 of Article 47 was inserted by Directive 2011/62/EU of the European Parliament and of the Council (OJ No L 174, 1.7.2011, p74).

- (e) the measures taken under this paragraph are documented by the licence holder.
- (6) The licence holder must maintain such staff, premises and equipment as are necessary for the stages of manufacture and assembly of medicinal products undertaken by the licence holder in accordance with—
- (a) the manufacturer’s licence; and
  - (b) the marketing authorisations, Article 126a authorisations, certificates of registration or traditional herbal registrations applying to the medicinal products.
- (7) The licence holder must not manufacture or assemble medicinal products, or classes of medicinal products, other than those specified in the licence.
- (8) The licence holder must not manufacture or assemble medicinal products on premises other than those specified in the licence as approved by the licensing authority for the purpose.
- (9) The licence holder must ensure that blood, or blood components, imported into the United Kingdom and used as a starting material or raw material in the manufacture of a medicinal product meet—
- (a) the standards of quality and safety specified in Commission Directive [2004/33/EC](#) of 22 March 2004 implementing Directive [2002/98/EC](#) of the European Parliament and of the Council as regards certain technical requirements for blood and blood components<sup>(11)</sup>; or
  - (b) equivalent standards.
- (10) The requirements in paragraphs (3) to (5) do not apply in relation to the manufacture or assembly of special medicinal product to which regulation 167 (supply to fulfil special needs) applies.
- (11) The licence holder must immediately inform the competent authority of a member State and, where applicable, the marketing authorisation holder, of medicinal products which come within the scope of manufacturing authorisation which the licence holder—
- (a) knows or suspects; or
  - (b) has reasonable grounds for knowing or suspecting,
- to be falsified.”

### **Amendment of regulation 39**

**12.** In regulation 39(8) (further requirements for manufacturer’s licence), for “44(2) and (3)” substitute “44(4) to (6)”.

### **Amendment of regulation 42**

**13.** In regulation 42 (conditions for wholesale dealer’s licence), for paragraph (2) substitute—  
“(2) Those provisions are regulations 43(2) and (8) and 44.”

### **Amendment of regulation 43**

**14.** In regulation 43 (obligations of licence holder)—  
(a) for paragraphs (7)(c) and (8) substitute—

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<sup>(11)</sup> OJ No L 91, 30.3.2004, p25; relevant amending instrument is Commission Implementing Directive 2011/38/EU (OJ No L 97, 12.4.2011, p28).

- “(c) keep records in relation to the receipt, dispatch or brokering of medicinal products, of—
- (i) the date of receipt,
  - (ii) the date of despatch,
  - (iii) the date of brokering,
  - (iv) the name of the medicinal product,
  - (v) the quantity of the product received, dispatched or brokered,
  - (vi) the name and address of the person from whom the products were received or to whom they are dispatched,
  - (vii) the batch number of medicinal products bearing safety features referred to in point (o) of Article 54(12) of the 2001 Directive.

(8) A licence holder (“L”) who imports from another EEA State a medicinal product in relation to which L is not the holder of a marketing authorisation, Article 126a authorisation, certificate of registration or a traditional herbal registration shall—

- (a) notify the intention to import that product to the holder of the authorisation and—
  - (i) in the case of a product which has been granted a marketing authorisation under Regulation (EC) No 726/2004, to the EMA; or
  - (ii) in any other case, the licensing authority; and
- (b) pay a fee to the EMA in accordance with Article 76(4)(13) of the 2001 Directive or the licensing authority as the case may be, in accordance with the Fees Regulations,

but this paragraph does not apply in relation to the wholesale distribution of medicinal products to a person in a third country.”;

(b) for paragraph (10) substitute—

**14.**—“(10) The holder (“L”) must verify in accordance with paragraph (11) that any medicinal products received by L that are required by Article 54a(14) of the Directive to bear safety features are not falsified but this paragraph does not apply in relation to the distribution of medicinal products received from a third country by a person to a person in a third country.

(11) Verification under this paragraph is carried out by checking the safety features on the outer packaging, in accordance with the requirements laid down in the delegated acts adopted under Article 54a(2) of the 2001 Directive.

(12) The licence holder must maintain a quality system setting out responsibilities, processes and risk management measures in relation to their activities.

(13) The licence holder must immediately inform the licensing authority and, where applicable, the marketing authorisation holder, of medicinal products which the licence holder receives or is offered which the licence holder—

- (a) knows or suspects; or
- (b) has reasonable grounds for knowing or suspecting,

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(12) Point (o) of Article 54 was inserted by Directive 2011/62/EU of the European Parliament and of the Council (OJ No L 174, 1.7.2011, p74).

(13) Article 76(4) was inserted by Directive 2011/62/EU of the European Parliament and of the Council (OJ No L 174, 1.7.2011, p74).

(14) Article 54a was inserted by Directive 2011/62/EU of the European Parliament and of the Council (OJ No L 174, 1.7.2011, p74).



to be falsified.

(14) Where the medicinal product is obtained through brokering, the licence holder must verify that the broker involved fulfils the requirements set out in regulation 45A(1)(b).

(15) In this regulation, “marketing authorisation” means—

- (a) a marketing authorisation issued by a competent authority in accordance with the 2001 Directive; or
- (b) an EU marketing authorisation.”

#### **Substitution of regulation 44**

**15.** For regulation 44 (requirement for wholesale dealers to deal only with specified persons) substitute—

##### **“Requirement for wholesale dealers to deal only with specified persons**

**44.—**(1) Unless paragraph (2) applies, the licence holder must not obtain supplies of medicinal products from anyone except—

- (a) the holder of a manufacturer’s licence or wholesale dealer’s licence in relation to products of that description;
- (b) the person who holds an authorisation granted by another EEA State authorising the manufacture of products of the description or their distribution by way of wholesale dealing; or
- (c) where the supplier is not the holder of a manufacturer’s licence, where the supply is in accordance with the principles and guidelines of good distribution practice,

but this paragraph does not apply in relation to the distribution of medicinal products directly received from a third country but not imported into the EU.

(2) From 28th October 2013 the licence holder must not obtain supplies of medicinal products from anyone except—

- (a) the holder of a manufacturer’s licence or wholesale dealer’s licence in relation to products of that description;
- (b) the person who holds an authorisation granted by another EEA State authorising the manufacture of products of the description or their distribution by way of wholesale dealing;
- (c) where the medicinal product is directly received from a third country (“A”) for export to a third country (“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; or
- (d) where the supplier is not the holder of a manufacturer’s licence, where the supply is in accordance with the principles and guidelines of good distribution practice.

(3) Where a medicinal product is obtained in accordance with paragraph (1), (2)(a) or (b), the licence holder must verify that—

- (a) the wholesale dealer who supplies the product complies with the principles and guidelines of good distribution practices; or
- (b) the manufacturer or importer who supplies the product holds a manufacturing authorisation.

(4) Unless paragraph (5) applies, the licence holder may distribute medicinal products by way of wholesale dealing only to—

- (a) the holder of a wholesale dealer's licence relating to those products;
- (b) the holder of an authorisation granted by the competent authority of another EEA State authorising the supply of those products by way of wholesale dealing;
- (c) a person who may lawfully sell those products by retail or may lawfully supply them in circumstances corresponding to retail sale; or
- (d) a person who may lawfully administer those products,

but this paragraph does not apply in relation to medicinal products which are distributed by way of wholesale dealing to a person in a third country.

(5) From 28th October 2013, the licence holder may distribute medicinal products by way of wholesale dealing only to—

- (a) the holder of a wholesale dealer's licence relating to those products;
- (b) the holder of an authorisation granted by the competent authority of another EEA State authorising the supply of those products by way of wholesale dealing;
- (c) a person who may lawfully sell those products by retail or may lawfully supply them in circumstances corresponding to retail sale;
- (d) a person who may lawfully administer those products; or
- (e) in relation to supply to persons in third countries, 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 third country concerned.

(6) Where a medicinal product is supplied to a person who is authorised or entitled to supply medicinal products to the public in accordance with paragraph (4)(c), (5)(c) or (e), the licence holder must enclose with the product a document stating the—

- (a) date on which the supply took place;
- (b) name and pharmaceutical form of the product supplied;
- (c) quantity of product supplied;
- (d) name and address of the licence holder; and
- (e) batch number of the medicinal products bearing the safety features referred to in point (o) of Article 54 of the 2001 Directive.

(7) The licence holder must—

- (a) keep a record of information supplied in accordance with paragraph (6) for at least five years beginning immediately after the date on which the information is supplied; and
- (b) ensure that the record is available to the licensing authority for inspection.”

#### **Insertion of regulations 45A to 45V**

16. At the end of regulation 45 insert—

## “CHAPTER 3

### Brokering

#### **Brokering in medicinal products**

- 45A.**—(1) A person may not broker a medicinal product unless—
- (a) that product is covered by an authorisation granted—
    - (i) under Regulation (EC) No 726/2004; or
    - (ii) by a competent authority of a member State; and
  - (b) that person—
    - (i) is validly registered as a broker with a competent authority of a member State,
    - (ii) except where the person is validly registered with the competent authority of another 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.
- (2) A person is not validly registered for the purpose of paragraph (1)(b) if—
- (a) the person’s permanent address is not entered into a register of brokers kept by a competent authority of a member State;
  - (b) the registration is suspended; or
  - (c) the person has notified the competent authority of a member State to remove that person from the register.
- (3) Paragraph (1)(b)(i) does not apply until 20th October 2013 in relation to a person who brokered any medicinal product before 20th August 2013.

#### **Application for brokering registration**

- 45B.**—(1) The licensing authority may not register a person as a broker unless paragraphs to (7) are complied with.
- (2) An application for registration must be made containing—
- (a) the name of the person to be registered;
  - (b) the name under which that person is trading (if different to the name of that person);
  - (c) that person’s—
    - (i) permanent address in the United Kingdom,
    - (ii) e-mail address, and
    - (iii) telephone number;
  - (d) a statement of whether the medicinal products to be brokered are—
    - (i) prescription only medicines,
    - (ii) pharmacy medicines, or
    - (iii) medicines subject to general sale;
  - (e) an indication of the range of medicinal products to be brokered;

- (f) evidence that that person can comply with regulations 45A(1)(b)(iii), 45E(3)(a) to (f) and 45F(1); and
  - (g) any fee payable in connection with the application in accordance with the Fees Regulations.
- (3) Where the address at which the emergency plan, documents or record necessary to comply with regulation 45E(3)(b) to (d) are kept is different from the address notified in accordance with sub-paragraph (2)(c)(i), the application must contain—
- (a) that address where the plan or records are to be kept;
  - (b) the name of a person who can provide access to that address for the purpose of regulation 325 (rights of entry); and
  - (c) that person’s—
    - (i) address,
    - (ii) e-mail address, and
    - (iii) telephone number.
- (4) Unless paragraph (6) applies, the application for registration must—
- (a) be in English; and
  - (b) be signed by the person seeking a brokering registration.
- (5) The pages of the application must be serially numbered.
- (6) Where the application is made on behalf of the person seeking a brokering registration by another person (“A”), the application must—
- (a) contain the name and address of A; and
  - (b) be signed by A.

#### **Procedure for determining an application for broker’s registration**

**45C.—**(1) The licensing authority must grant or refuse an application for registration under regulation 45B within the period of 90 days beginning immediately after the day on which it receives the application.

(2) Paragraph (1) applies to an application only if the requirements of regulation 45B(2) have been met.

(3) Before determining an application for a brokering registration, the licensing authority may notify the applicant of a requirement to provide such information as the licensing authority thinks necessary, within the period specified by the licensing authority.

(4) If a notice under paragraph (3) requires the applicant to provide the licensing authority with information, the information period is not to be counted for the purposes of paragraph (1).

(5) In paragraph (4), the “information period” means the period—

- (a) beginning with the day on which the notice is given, and
- (b) ending with the day on which the licensing authority receives the information or the applicant shows to the licensing authority’s satisfaction that the applicant is unable to provide it.

### **Grant or refusal of broker's registration**

**45D.**—(1) Subject to regulations 45E and 45F, on an application to the licensing authority for a brokering registration, the licensing authority must, if it considers it necessary and appropriate to do so—

- (a) register the applicant as a broker; or
- (b) refuse registration as a broker, having regard to—
  - (i) the provisions of these Regulations, and
  - (ii) any EU obligation.

(2) The licensing authority must give the applicant a notice stating the reasons for its decision in any case where the licensing authority—

- (a) refuses to grant an application for registration; or
- (b) grants registration otherwise than in accordance with the application and the applicant requests a statement of its reasons.

(3) The licensing authority must register the applicant or refuse registration under this Chapter within the period of 90 days beginning immediately after the day on which it receives the application.

(4) Where the licensing authority registers a person as a broker, the licensing authority must enter the following information into a publicly available register—

- (a) the person's name;
- (b) the name under which that person is trading (if different from the person's name);
- (c) the person's permanent address in the United Kingdom.

(5) The licensing authority must make the register of brokers publicly available.

### **Criteria of broker's registration**

**45E.**—(1) Registration of a broker is conditional on that broker—

- (a) complying with regulation 45A(1); and
- (b) satisfying—
  - (i) the criteria in paragraphs (3), (4) and (7), and
  - (ii) such other criteria as the licensing authority considers appropriate and notifies the broker of.

(2) The criteria referred to in paragraph (1)(b)(ii) may include (but are not limited to) the criteria specified in paragraphs (5) and (6).

(3) The broker must—

- (a) have a permanent address in the United Kingdom;
- (b) maintain an emergency plan to ensure effective implementation of the recall from the market of a medicinal product where recall is—
  - (i) ordered by the licensing authority or by the competent authority of any EEA State, or
  - (ii) carried out in co-operation with the manufacturer of, or the holder of the marketing authorisation, for the product;
- (c) keep documents relating to the sale or supply of medicinal products under the licence which may facilitate the withdrawal or recall from sale of medicinal products in accordance with sub-paragraph (b);

- (d) record in relation to the brokering of each medicinal product—
  - (i) the name of the medicinal product,
  - (ii) the quantity of the product brokered,
  - (iii) the batch number of the medicinal product bearing the safety features referred to in point (o) of Article 54 of the 2001 Directive,
  - (iv) the name and address of the—
    - (aa) supplier, or
    - (bb) consignee, and
  - (v) the date on which the sale or purchase of the product is brokered;
- (e) maintain a quality system setting out responsibilities, processes and risk management measures in relation to their activities; and
- (f) keep the documents or record required by sub-paragraph (c) or (d) available to the licensing authority for a period of five years; and
- (g) comply with regulation 45F(1), (2) and (4).

(4) Where the address at which the plan or records necessary to comply with paragraph (3)(b) to (d) are kept is different from the address notified in accordance with regulation 45B(2)(c)(i), the broker must—

- (a) ensure that the plan or records are kept at an address in the United Kingdom; and
- (b) inform the licensing authority of the address at which the plan or records are kept.

(5) The broker must provide such information as may be requested by the licensing authority concerning the type and quantity of medicinal products brokered within the period specified by the licensing authority.

(6) The broker must take all reasonable precautions and exercise all due diligence to ensure that any information provided by that broker to the licensing authority in accordance with regulation 45F is not false or misleading.

(7) For the purposes of enabling the licensing authority to determine whether there are grounds for suspending, revoking or varying the registration, the broker must permit a person authorised in writing by the licensing authority, on production of identification, to carry out any inspection, or to take any copies, which an inspector may carry out or take under regulations 325 (rights of entry) and 327 (powers of inspection, sampling and seizure).

### **Provision of information**

**45F.—**(1) A broker registered in the UK must immediately inform—

- (a) the licensing authority; and
- (b) where applicable, the marketing authorisation holder,

of medicinal products which the broker identifies as, suspects to be, or has reasonable grounds for knowing or suspecting to be, falsified.

(2) On or before the date specified in paragraph (3), a broker who is, or has applied to the licensing authority to become, a registered broker in the United Kingdom must submit a report to the licensing authority, which—

- (a) includes a declaration that the broker has in place an appropriate system to ensure compliance with regulations 45A, 45B and this regulation; and
- (b) details the system which the broker has in place to ensure such compliance.

(3) The date specified for the purposes of this paragraph is—

- (a) in relation to any application made before 31st March 2014, the date of the application; and
- (b) in relation to each subsequent reporting year, 30th April following the end of that year.

(4) The broker must without delay notify the licensing authority of any changes to the matters in respect of which evidence has been supplied in relation to paragraph (2) which might affect compliance with the requirements of this Chapter.

(5) Any report or notification to the licensing authority under paragraph (2) or (4) must be accompanied by the appropriate fee in accordance with the Fees Regulations.

(6) The licensing authority may give a notice to a registered broker requiring that broker to provide information of a kind specified in the notice within the period specified in the notice.

(7) A notice under paragraph (6) may not be given to a registered broker unless it appears to the licensing authority that it is necessary for the licensing authority to consider whether the registration should be varied, suspended or revoked.

(8) A notice under paragraph (6) may specify information which the licensing authority thinks necessary for considering whether the registration should be varied, suspended or revoked.

(9) In paragraph (3)(b), “reporting year” means a period of twelve months ending on 31st March.

#### **Power to suspend or vary a broker’s registration or remove a broker from the register**

**45G.**—(1) The licensing authority may in accordance with regulation 45H—

- (a) suspend a broker’s registration for such period as the authority thinks fit;
- (b) vary a broker’s registration; or
- (c) remove a person from the register.

(2) The suspension of registration or removal from the register may be—

- (a) total;
- (b) limited to medicinal products of one or more descriptions; or
- (c) limited to medicinal products manufactured, assembled or stored on specified premises or a specified part of any premises.

(3) The powers conferred by this regulation may not be exercised in relation to a broker’s registration except on one or more of the following grounds—

- (a) the information in the application as a result of which the broker’s registration was granted was false or incomplete in a material respect;
- (b) a material change of circumstances has occurred in relation to any of the matters stated in the application;
- (c) the broker has materially contravened a criterion of registration; or
- (d) the broker has without reasonable excuse failed to supply information to the licensing authority with respect to medicinal products of a description to which the registration relates when required to do so under regulation 45F(6).

**Procedure where licensing authority proposes to suspend or vary a broker's registration or remove a broker from the register**

- 45H.**—(1) This regulation applies where—
- (a) regulation 45I does not apply; and
  - (b) the licensing authority proposes to exercise the power in regulation 45G(1).
- (2) The licensing authority must notify the broker in writing of—
- (a) its proposal;
  - (b) the reasons for it; and
  - (c) the date (which must be no earlier than 28 days from the notice given by the licensing authority) on which it is proposed that the suspension, variation or revocation should take effect.
- (3) The registered broker may before the date specified in the notice—
- (a) make written representations to the licensing authority with respect to the proposal; or
  - (b) notify the licensing authority that the broker wishes the licensing authority to submit the proposal to review upon oral representations.
- (4) If the broker makes written representations in accordance with paragraph (3)(a) the licensing authority must take those representations into account before making a decision in the matter.
- (5) Schedule 5 has effect if the registered broker—
- (a) notifies the licensing authority of the proposal to review upon oral representations in accordance with paragraph (3)(b); and
  - (b) pays the fee for a review upon oral representations in accordance with the Fees Regulations.
- (6) If the licensing authority proceeds to suspend or vary a registration or remove a broker from the register in accordance with the provisions of regulation 45G it must give a notice to the broker.
- (7) A notice under paragraph (6) must—
- (a) give particulars of the suspension, variation or removal; and
  - (b) give reasons for the decision to suspend, vary or remove a broker from the register.
- (8) Paragraphs (6) and (7) are without prejudice to any requirement of Schedule 5 as to notification.

**Suspension of a broker registration in cases of urgency**

- 45I.**—(1) The licensing authority may immediately suspend a broker's registration for a period not exceeding three months where it appears to the licensing authority that in the interests of safety it is appropriate to do so.
- (2) This paragraph applies where—
- (a) a broker's registration has been suspended under paragraph (1); and
  - (b) it appears to the licensing authority that it is necessary to consider whether the broker's registration should be—
    - (i) further suspended or varied, or
    - (ii) removed from the brokers' register.



(3) Where paragraph (2) applies, the licensing authority must proceed as set out in regulation 45H (but this is subject to paragraph (4)).

(4) Paragraph (5) applies where, in circumstances where paragraph (2) applies, the licensing authority proceeds as set out in regulation 45H and any proceedings under that regulation have not been finally disposed of before the end of the period for which the registration was suspended under paragraph (1) or further suspended under paragraph (5).

(5) If it appears to the licensing authority to be necessary in the interests of safety to do so, the authority may further suspend the registration for a period which (in the case of each further suspension) is not to exceed three months.

(6) In the event that any challenge against a decision under regulation 45H to suspend, vary or revoke the registration is made on an application under regulation 322(4), paragraph (5) shall apply, but this is without prejudice to regulation 322(6)(a) (validity of decisions and proceedings).

### **Variation of a broker's registration on the application of the broker**

**45J.**—(1) This regulation applies if the person registered as a broker applies to the licensing authority for a variation of the registration.

(2) The application must—

- (a) be in writing;
- (b) specify the variation requested;
- (c) be signed by or on behalf of the applicant;
- (d) be accompanied by such information as may be required to enable the licensing authority to consider the application;
- (e) include the appropriate fee in accordance with the Fees Regulations.

(3) The licensing authority must vary a broker's registration or refuse to vary it within 30 days beginning with the day after the date when the licensing authority receives the application.

(4) The licensing authority may give a notice to the applicant requiring the applicant to supply further information in connection with the application within the period specified in the notice.

(5) If a notice under paragraph (4) requires the applicant to provide the licensing authority with information, the information period is not to be counted for the purposes of paragraph (3).

(6) In paragraph (5), the "information period" means the period—

- (a) beginning with the day on which notice is given; and
- (b) ending with the day on which the licensing authority receives the information or the applicant shows to the licensing authority's satisfaction that the applicant is unable to provide it.

(7) Nothing in this regulation affects the powers conferred by regulations 45G and 45I.

### **Offences: breach of regulations and false information**

**45K.**—(1) A person is guilty of an offence if the person—

- (a) contravenes regulation 45A(1); or
- (b) brokers a medicinal product otherwise than in accordance with the criteria under regulation 45E relating to that person's brokering registration.

- (2) A person is guilty of an offence if the person knowingly gives false information in—
- (a) an application for a broker registration under regulation 45B(2);
  - (b) a notification to the licensing authority under regulation 45F(4);
  - (c) an application for a variation under regulation 45J(1); or
  - (d) response to a notice under regulation 45C(3) or 45J(5).
- (3) A person is guilty of an offence if, without reasonable excuse, the person fails to comply with a notice under regulation 45F(6) or 45J(5).

### **Penalties**

- 45L.**—(1) A person guilty of an offence under regulation 45K(1) or (2) is liable—
- (a) on summary conviction to a fine not exceeding the statutory maximum; or
  - (b) on conviction on indictment to a fine, to imprisonment for a term not exceeding two years, or to both.
- (2) A person guilty of an offence under regulation 45K(3) is liable on summary conviction to a fine not exceeding level 3 on the standard scale.

## **CHAPTER 4**

### Importation, manufacture and distribution of active substances

#### **Criteria for importation, manufacture or distribution of active substances**

- 45M.**—(1) A person may not—
- (a) import;
  - (b) manufacture; or
  - (c) distribute,
- an active substance unless that person is registered with the licensing authority in accordance with regulation 45N and the requirements in regulation 45O are met.
- (2) Paragraph (1) applies in relation to an active substance which is to be used in an investigational medicinal product only—
- (a) if the product has a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration; and
  - (b) to the extent that the manufacture of the active substance is in accordance with the terms and conditions of that authorisation, certificate or registration.
- (3) Paragraph (1)(a) does not apply to a person who, in connection with the importation of an active substance from a state other than an EEA state—
- (a) provides facilities solely for transporting the active substance; or
  - (b) acting as an import agent, imports the active substance solely to the order of another person who holds a certificate of good manufacturing practice issued by the licensing authority.

#### **Registration in relation to active substances**

- 45N.**—(1) For registration in relation to active substances, the licensing authority must have received a valid registration form from the applicant for import, manufacture or, as the case may be, distribution of an the active substance and—

- (a) 60 days have elapsed since receipt and the licensing authority have not notified the applicant that an inspection will be carried out; or
  - (b) the licensing authority—
    - (i) notified the applicant within 60 days of receipt of a registration form that an inspection will be carried out; and
    - (ii) within 90 days of that inspection the licensing authority have issued that person with a certificate of good manufacturing practice or, as the case may be, of good distribution practice; and
  - (c) that person has not instructed the licensing authority to end that person's registration.
- (2) The person applying for registration under paragraph (1) must notify the licensing authority of any changes which have taken place as regards the information in the registration form—
- (a) immediately where such changes may have an impact on quality or safety of the active substances that are manufactured, imported or distributed;
  - (b) in any other case, on each anniversary of the receipt of the application form by the licensing authority.
- (3) For the purpose of paragraph (2), changes which are notified in accordance with that paragraph shall be treated as incorporated in the application form.
- (4) Any notification to the licensing authority under paragraph (2) must be accompanied by the appropriate fee in accordance with the Fees Regulations.
- (5) A registration form is valid for the purpose of paragraph (1) if—
- (a) it is provided to the licensing authority; and
  - (b) is completed in the way and form specified in Schedule 7A.
- (6) Paragraph (1) does not apply until 20th October 2013 in relation to a person who had, before 20th August 2013, commenced the activity for which the person would, apart from this provision, need to send a registration form to the licensing authority.

#### **Requirements for registration as an importer, manufacturer or distributor of an active substance**

**450.**—(1) Where the Commission has adopted principles and guidelines of good manufacturing practice under the third paragraph of Article 47(15) of the 2001 Directive which applies to an active substance manufactured in the UK, the manufacturer must comply with good manufacturing practice in relation to that active substance.

(2) 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 United Kingdom, the distributor must comply with good distribution practice in relation to that active substance.

(3) Without prejudice to regulation 37(4) (manufacture and assembly in relation to active substances) and paragraph 9A of Schedule 8 (material to accompany an application for a UK marketing authorisation in relation to an active substance), 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 imported into the UK and where an active substance is imported from a third country—

- (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 third 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 the Union, and
    - (iii) in the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country to the Union without any delay.
- (4) Paragraph (3)(c) does not apply—
- (a) where the country from where the active substance is exported is included in the list referred to in Article 111b of the 2001 Directive; or
  - (b) for a period not exceeding the validity of the certificate of good manufacturing practice, where—
    - (i) in relation to a plant where active substances are manufactured where the competent authority of a member State has found, upon inspection, that a plant complies with the principles and guidelines of good manufacturing practice, and
    - (ii) the licensing authority is of the opinion that it is necessary to waive the requirement to ensure availability of the active substance.
- (5) The criteria in this regulation apply regardless of whether an active substance is intended for export.

### **Provision of information**

**45P.**—(1) In this regulation—

“R” means a person who is, or has applied to the licensing authority to become, a registered importer, manufacturer or distributor of active substances;

“reporting year” means a period of twelve months ending on 31st March.

- (2) On or before the date specified in paragraph (3), R must submit a report to the licensing authority which—
- (a) includes a declaration that R has in place an appropriate system to ensure compliance with regulations 45N, 45O and this regulation; and
  - (b) details the system which R has in place to ensure such compliance.
- (3) The date specified for the purposes of this paragraph is—
- (a) in relation to any application made before 31st March 2014, the date of the application; and
  - (b) in relation to each subsequent reporting year, 30th April following the end of that year.

(4) R must without delay notify the licensing authority of any changes to the matters in respect of which evidence has been supplied in relation to paragraph (2) which might affect compliance with the requirements of this Chapter.

(5) Any report or notification to the licensing authority under paragraph (2) or (4) must be accompanied by the appropriate fee in accordance with the Fees Regulations.

(6) The licensing authority may give a notice to R, requiring R to provide information of a kind specified in the notice within the period specified in the notice.

(7) A notice under paragraph (6) may not be given to R unless it appears to the licensing authority that it is necessary for the licensing authority to consider whether the registration should be varied, suspended or removed from the active substance register.

(8) A notice under paragraph (6) may specify information which the licensing authority thinks necessary for considering whether the registration should be varied, suspended or removed from the active substance register.

#### **Power to suspend or vary or remove an active substance registration**

**45Q.**—(1) The licensing authority may in accordance with regulation 45R—

- (a) suspend an active substance registration for such period as the authority thinks fit;
- (b) vary an active substance registration; or
- (c) remove a person from the active substance register.

(2) The suspension of registration may be—

- (a) total;
- (b) limited to active substances of one or more descriptions; or
- (c) limited to active substances imported, manufactured, assembled or stored on specified premises or a specified part of any premises.

(3) The powers conferred by this regulation may not be exercised in relation to an active substance registration except on one or more of the following grounds—

- (a) the information in the application as a result of which the active substance registration was granted was false or incomplete in a material respect;
- (b) a material change of circumstances has occurred in relation to any of the matters stated in the application;
- (c) the person with an active substance registration has materially contravened a criterion of registration; or
- (d) the person with an active substance registration has without reasonable excuse failed to supply information to the licensing authority with respect to active substances of a description to which the registration relates when required to do so under regulation 45P(6).

#### **Procedure where licensing authority proposes to suspend or vary an active substance registration or remove a person from the active substance register**

**45R.**—(1) This regulation applies where—

- (a) the provisions of regulation 45S do not apply; and
- (b) the licensing authority proposes to exercise the power in regulation 45Q(1).

(2) The licensing authority must notify the person with an active substance registration in writing of—

- (a) its proposal;
  - (b) the reasons for it; and
  - (c) the date (which must be no earlier than 28 days from the notice given by the licensing authority) on which it is proposed that the suspension, variation or removal from the active substance register should take effect.
- (3) The person with an active substance registration may before the date specified in the notice—
- (a) make written representations to the licensing authority with respect to the proposal; or
  - (b) notify the licensing authority that the person wishes the licensing authority to submit the proposal to review upon oral representations.
- (4) If the person with an active substance registration makes written representations in accordance with sub-paragraph (3)(a) the licensing authority must take those representations into account before making a decision in the matter.
- (5) If the person with an active substance registration notifies the licensing authority that the person wishes the licensing authority to submit the proposal to review upon oral representations in accordance with paragraph (3)(b)—
- (a) Schedule 5 has effect; and
  - (b) the person with an active substance registration must pay a fee for a review upon oral representations in accordance with the Fees Regulations.
- (6) If the licensing authority proceeds to suspend or vary a registration or remove a person from the active substance register in accordance with the provisions of regulation 45Q it must give a notice to that person.
- (7) The notice must—
- (a) give particulars of the suspension, variation or removal; and
  - (b) give reasons for the decision to suspend, vary or remove a person's entry on the active substance register.
- (8) Paragraphs (6) and (7) are without prejudice to any requirement of Schedule 5 as to notification.

### **Suspension of an active substance registration in cases of urgency**

**45S.**—(1) The licensing authority may immediately suspend a person's active substance registration for a period not exceeding three months where it appears to the licensing authority that in the interests of safety it is appropriate to do so.

- (2) This paragraph applies where—
- (a) a person's active substance registration has been suspended under paragraph (1); and
  - (b) it appears to the licensing authority that it is necessary to consider whether a person's active substance registration should be—
    - (i) further suspended or varied, or
    - (ii) removed from the active substance register.
- (3) Where paragraph (2) applies, the licensing authority must proceed as set out in regulation 45R (but this is subject to paragraph (4)).
- (4) Paragraph (5) applies where, in circumstances where paragraph (2) applies, the licensing authority proceeds as set out in regulation 45R and any proceedings under that

regulation have not been finally disposed of before the end of the period for which the registration was suspended under paragraph (1) or further suspended under paragraph (5).

(5) If it appears to the licensing authority to be necessary in the interests of safety to do so, the authority may further suspend the registration for a period which (in the case of each further suspension) is not to exceed three months.

(6) In the event that any challenge against a decision under regulation 45R to suspend, vary or remove a person's active substance registration is made on an application to the High Court under regulation 322(4), paragraph (5) shall apply, but this is without prejudice to regulation 322(6)(a) (validity of decisions and proceedings).

### **Variation of an active substance registration on an application from the registered person**

**45T.**—(1) This regulation applies if a person with an active substance registration applies to the licensing authority for a variation of the registration.

(2) The application must—

- (a) be in writing;
- (b) specify the variation requested;
- (c) be signed by or on behalf of the applicant;
- (d) be accompanied by such information as may be required to enable the licensing authority to consider the application; and
- (e) include the appropriate fee in accordance with the Fees Regulations.

(3) The licensing authority must vary an active substance registration or refuse to vary it within 30 days beginning with the day after the date when the licensing authority receives the application.

(4) The licensing authority may give a notice to the applicant requiring the applicant to supply further information in connection with the application within the period specified in the notice.

(5) If a notice under paragraph (4) requires the applicant to provide the licensing authority with information, the information period is not to be counted for the purposes of paragraph (3).

(6) In paragraph (5), the “information period” means the period—

- (a) beginning with the day on which notice is given; and
- (b) ending with the day on which the licensing authority receives the information or the applicant shows to the licensing authority's satisfaction that the applicant is unable to provide it.

(7) Nothing in this regulation affects the powers conferred by regulations 45Q and 45S.

### **Offences: breach of regulations and false information**

**45U.**—(1) A person is guilty of an offence if the person imports, manufactures or distributes an active substance in breach of regulation 45M(1).

(2) A person is guilty of an offence if the person knowingly gives false information in—

- (a) a registration form received by the licensing authority under regulation 45N(1);
- (b) a notification to the licensing authority under regulation 45N(2) or 45P(4);
- (c) an application for a variation under regulation 45T(2); or

(d) response to a notice under regulation 45T(4).

(3) A person is guilty of an offence if, without reasonable excuse, the person fails to comply with a notice under regulation 45P(6) or 45T(4).

#### **Penalties**

**45V.**—(1) A person guilty of an offence under regulation 45U(1) or (2) is liable—

- (a) on summary conviction to a fine not exceeding the statutory maximum; or
- (b) on conviction on indictment to a fine, to imprisonment for a term not exceeding two years, or to both.

(2) A person guilty of an offence under regulation 45U(3) is liable on summary conviction to a fine not exceeding level 3 on the standard scale.”

#### **Amendment of regulation 68**

**17.** In regulation 68 (revocation, variation and suspension of UK marketing authorisation), after paragraph (11) insert—

“(11A) Condition K is that the manufacture of the product to which the authorisation relates is not carried out in compliance with the particulars provided under paragraphs 5 and 9 of Schedule 8.”

#### **Amendment of regulation 84**

**18.** In regulation 84 (EU marketing authorisations: failure to provide information as to safety etc), in paragraph (2) for “16(4)” substitute “16(3a)(**16**)”.

#### **Amendment of regulation 110**

**19.** In regulation 110 (revocation, variation and suspension of certificate of registration), after paragraph (8) insert—

“(8A) Condition H is that the manufacture and control of the product to which the certificate relates is not in compliance with the particulars provided under regulation 103(8) (c) and (d).”

#### **Amendment of regulation 135**

**20.** In regulation 135 (revocation, variation and suspension of traditional herbal registration), after paragraph (10) insert—

“(10A) Condition J is that the manufacture of the product to which registration relates is not carried out in compliance with the particulars provided under paragraphs 5 and 9 of Schedule 12.”

#### **Amendment of regulation 177**

**21.**—(1) Regulation 177 (application of Part 11 and interpretation) is amended as follows.

(2) For paragraph (4) substitute—

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(16) Article 16(4) of Regulation (EC) No 726/2004 was re-numbered as Article 16(3a) by virtue of the Corrigendum (OJ L 348, 31.12.2010, p1) to Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicines for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medical Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products.



“(4) The following provisions of this Part and Schedule 33 apply in relation to medicinal products that are the subject of an EU marketing authorisation—

- (a) regulation 206 (infringement notices);
- (b) regulation 210 (offences relating to pharmacovigilance obligations under Regulation (EC) No 726/2004), and paragraphs 2 and 4 of Schedule 33 (transitional arrangements: pharmacovigilance), but that regulation and those paragraphs do not apply in relation to the medicinal products specified in paragraph (1); and
- (c) regulation 210A (offences in relation to pharmacovigilance obligations under the Implementing Regulation).”

(3) In paragraph (5) after the definition of “Eudravigilance database” insert—

““Implementing Regulation” means Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council(17).”

#### **Amendment of regulation 182**

**22.** In regulation 182 (obligation on holder to operate pharmacovigilance system), in paragraph (3) omit “and the EMA”.

#### **Amendment of regulation 206**

**23.**—(1) Regulation 206 (infringement notices) is amended as follows.

(2) For paragraph (1) substitute—

“(1) If an enforcement authority has objective grounds for considering that any person (“P”) has contravened any relevant provision, it may serve upon P a notice in writing (referred to in this Part as an “infringement notice”)—

- (a) informing P of the authority’s grounds for considering that P has contravened one or more relevant provision;
- (b) specifying the relevant provision;
- (c) specifying the measures which P must take in order to ensure that the contravention does not continue or, as the case may be, does not recur;
- (d) requiring P to take those measures, within such period as may be specified in the notice;
- (e) specifying the further action (if any) that the enforcement authority may take.”

(3) After paragraph (3) insert—

“(4) In this regulation “relevant provision” means a provision of—

- (a) this Part;
- (b) Chapter 3 of Title II of Regulation (EC) No 726/2004; or
- (c) the Implementing Regulation.”

#### **Amendment of regulation 210**

**24.** In regulation 210 (offences relating to pharmacovigilance obligations under Regulation (EC) No 726/2004), in paragraphs (3)(a) and (6)(a) for “16(4)” substitute “16(3a)”.

## Insertion of regulation 210A

25. After regulation 210 insert—

### “Offences in relation to pharmacovigilance obligations under the Implementing Regulation

- 210A.**—(1) A holder is guilty of an offence if the holder—
- (a) fails to comply with any requirement or obligation contained in a provision of the Implementing Regulation listed in paragraph (2); or
  - (b) provides information which is false or misleading in a material particular to the licensing authority or the EMA pursuant to an obligation in the Implementing Regulation.
- (2) The provisions mentioned in paragraph (1)(a) are—
- (a) Chapter I (pharmacovigilance system master file)(**18**);
  - (b) Sections 1 and 2 of Chapter II (minimum requirements for the quality systems for the performance of pharmacovigilance activities)(**19**);
  - (c) Chapter III (minimum requirements for the monitoring of data in the Eudravigilance database)(**20**);
  - (d) Chapter V (transmission of reports of suspected adverse reactions)(**21**);
  - (e) Article 32 of Chapter VI (updates of risk management plans)(**22**);
  - (f) Chapter VII (periodic safety update reports)(**23**); and
  - (g) Chapter VIII (post-authorisation safety studies)(**24**).
- (3) Subject to paragraph (4), a person guilty of an offence under this regulation is liable—
- (a) on summary conviction to a fine not exceeding the statutory maximum; or
  - (b) on conviction on indictment to a fine.
- (4) A person guilty of an offence under this regulation which relates to a breach of Article 34(5) or 36(3) of the Implementing Regulation is liable—
- (a) on summary conviction to a fine not exceeding the statutory maximum; or

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- (18) Chapter I imposes requirements and obligations on holders in relation to the following aspects of the pharmacovigilance system master file: structure (Article 1), content (Article 2 and 3), maintenance and notification of certain changes (Article 4), form of documents contained in the pharmacovigilance system master file (Article 5) and availability and location (Article 7). Chapter I also imposes requirements on holders in relation to the sub-contracting of pharmacovigilance responsibilities (Article 6) and the submission of a logbook (Article 7).
- (19) Chapter II imposes requirements and obligations on holders in relation to the following aspects of the pharmacovigilance quality system: general matters (Article 8), content (Article 8(2)), basis of system (Article 8(3)), documentation (Article 8(4)), resource management (Article 10), compliance management (Article 11), record management (Article 12) and audit (Article 13).
- (20) Chapter III imposes requirements and obligations on holders in relation to the following aspects of monitoring data in the Eudravigilance database: general matters (Article 18), identification of new and changed risks (Article 19), methodology for determining signal value (Article 20) and signal management process (Article 21).
- (21) Chapter V imposes requirements and obligations on holders in relation to the following aspects of transmitting suspected adverse reaction reports: use of individual case safety reports (Article 27), content of individual case safety reports (Article 28) and format of electronic transmission (Article 29).
- (22) Article 32 in Chapter VI imposes requirements and obligations on holders in relation to updated risk management plans, including a requirement that updated risk management plans are submitted to the national competent authority.
- (23) Chapter VII imposes requirements and obligations on holders in relation to the following aspects of periodic safety update reports: content (Article 34) and format (Article 35).
- (24) Chapter VIII imposes requirements and obligations on holders in relation to the following aspects of post-authorisation safety studies: language of study information (Article 36(2)), handling and storage of study information (Article 36(3)) and format of study information (Article 38).

- (b) on conviction on indictment to a fine, to imprisonment for a term not exceeding two years or to both.”

#### **Amendment of regulation 214**

**26.** In regulation 214 (sale or supply of prescription only medicines), after paragraph (5) insert—

“(5A) A podiatrist independent prescriber is an appropriate practitioner in relation to any prescription only medicine unless that medicinal product contains a controlled drug other than—

- (a) Dihydrocodeine; or
- (b) Temazepam.

(5B) A physiotherapist independent prescriber is an appropriate practitioner in relation to any prescription only medicine unless that medicinal product contains a controlled drug other than—

- (a) Dihydrocodeine;
- (b) Fentanyl;
- (c) Morphine;
- (d) Oxycodone; or
- (e) Temazepam.”

#### **Amendment of regulation 223**

**27.** In regulation 223 (exemptions for doctors and dentists etc), for paragraphs (3)(b)(vi) and (vii) substitute—

- “(vi) a nurse independent prescriber,
- (vii) a community practitioner nurse prescriber,
- (viii) a podiatrist independent prescriber, or
- (ix) a physiotherapist independent prescriber.”

#### **Insertion of regulations 256A to 256N**

**28.** Immediately after regulation 256 (disqualification on conviction), insert—

### **“PART 12A**

#### **Sale of medicines to the public at a distance**

##### **Interpretation**

**256A.** In this Part—

“common logo” means the common logo that is required to be clearly displayed on websites offering medicinal products for sale at a distance to the public in accordance with the requirements laid down in the implementing acts adopted by the Commission under Article 85c(3)(25) of the 2001 Directive;

“information society services” means information society services as defined in Article 1(2) of Directive [98/34/EC](#)(**26**) of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services;

“the list” means the list of persons who are entitled to supply medicinal products by information society services that is maintained on the website of the competent authority of a member State in which the person named on the list is established;

“relevant website of the member State” means a website of the competent authority of a member State providing information on—

- (a) the national legislation applicable to the offering of medicinal products for sale at a distance to the public by information society services;
- (b) the differences between member States regarding classification of medicinal products and the conditions for their supply;
- (c) the purpose of the common logo;
- (d) the list of persons offering medicinal products for sale at a distance by means of information society services as well as their website addresses;
- (e) background information about the risks related to medicinal products supplied illegally to the public by means of information society services;
- (f) a hyperlink to the website of the EMA;

“website of the EMA” means the website of the EMA that—

- (a) gives explicit information to the viewer on the relevant website of the member State containing information on persons authorised or entitled to supply medicinal products at a distance in that member State;
- (b) provides information on the purpose of the common logo;
- (c) provides background information about the risks related to medicinal products supplied illegally to the public by means of information society services;
- (d) provides information on Community legislation applicable to falsified medicinal products;
- (e) contains hyperlinks to the relevant website of the member State.

### **Person who may sell medicinal products by information society services**

**256B.**—(1) A person may not sell a medicinal product at a distance to the public by means of information society services unless that person satisfies the following conditions.

(2) Condition A is that the person is included on the list of persons selling medicinal products at a distance that is published on the relevant website of the member State.

(3) Condition B is that the product to be sold by information society services is covered by an authorisation granted—

- (a) under Regulation [\(EC\) No 726/2004](#); or
- (b) by a competent authority of the member State in which that product is destined to be sold.

(4) Condition C is that the person selling the medicinal product is authorised or entitled to sell to the public, including by information society services, medicinal products of that type or classification in the member State in which that person is established.

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(26) OJ No L 204, 21.7.98, p37; relevant amending instrument is Directive [1998/48/EC](#) of the European Parliament and of the Council (OJ No L 217, 5.8.98, p18).

(5) Condition D is that where the sale is to a member of the public in the United Kingdom, it is in accordance with regulations 214 (sale or supply of prescription only medicines), 220 (sale or supply of medicinal products not subject to general sale) and 221 (sale or supply of medicinal products subject to general sale).

(6) Condition E is that the person selling the medicinal product has given a valid notification to the competent authority in a member State in which the person is established.

(7) Condition F is that the person selling medicinal products at a distance complies with the relevant provisions of the Electronic Commerce (EC Directive) Regulations 2002(27).

- (8) A person has not given a valid notification for the purposes of paragraph (6) if—
- (a) that person is not included on the list;
  - (b) the notification from that person is suspended by the competent authority of a member State; or
  - (c) the competent authority of a member State has been notified under regulation 256E(b) to remove that person from the list.

#### **Notification requirements for sellers of medicinal products at a distance**

**256C.**—(1) The competent authority of a member State may not enter a person's details on the list unless it has been notified in accordance with paragraphs to (5).

- (2) The notification must include—
- (a) the name or corporate name of the person to be listed;
  - (b) information about—
    - (i) that person's permanent address from which the activity of selling medicinal products by information society services is to be carried out,
    - (ii) the commencement date of the activity of selling medicinal products by information society services,
    - (iii) the address of the website used for the purposes of selling medicinal products by information society services,
    - (iv) all relevant information necessary to identify the website, and
    - (v) information about the classification of all the medicinal products offered for sale at a distance.
- (3) The notification shall—
- (a) be in English; and
  - (b) unless paragraph (4) applies, in relation to the person whose details are to be entered on the list—
    - (i) be signed by that person, and
    - (ii) contain that person's telephone number and e-mail address if this is available.
- (4) Where the notification is made by another person ("A") on behalf of the person whose details are to be entered on the list, the notification shall—
- (a) contain the name and address of A;
  - (b) be signed by A; and
  - (c) contain the telephone number and e-mail address for A if this is available.

(5) The notification shall contain contact details for the site from which the activity of selling medicinal products by information society services is to be carried out including the —

- (a) site address;
- (b) name of person who may be contacted; and
- (c) the telephone number and e-mail address of the person who may be contacted.

#### **Procedure for listing persons who may supply medicinal products at a distance**

**256D.**—(1) If the competent authority of a member State receives a notification under regulation 256C it must accept or refuse to include that person on the list within the period of 90 days beginning immediately after the day on which the notification is received by the authority.

(2) Paragraph (1) applies only if the requirements of regulation 256C(2) have been met.

(3) Before determining if a person can be included on the list, the competent authority of a member State may require the person giving the notification to provide such information as that competent authority thinks necessary, within the period specified by that competent authority.

(4) If a notice under paragraph (3) requires the person giving the notification to provide the competent authority of a member State with information, the information period is not to be counted for the purposes of paragraph (1).

(5) In paragraph (4), the “information period” means the period—

- (a) beginning with the day on which the notice is given, and
- (b) ending with the day on which—
  - (i) the competent authority of a member State receives the information; or
  - (ii) the person from whom the information is requested shows to the satisfaction of the competent authority of a member State that the information cannot be provided.

(6) The competent authority of a member State must give the person giving the notification a notice stating reasons for its decision in any case where—

- (a) the competent authority of a member State refuses to include the person giving the notification on the list; or
- (b) if the competent authority of a member State lists the person giving the notification otherwise that in accordance with the information supplied in the notification.

#### **Removal of a person’s entry from the list**

**256E.** The competent authority of a member State may remove a person’s entry from the list if—

- (a) regulation 256I(1)(b) applies; or
- (b) a notification to remove the entry is received from the person on the list.

#### **Provision of information to the competent authority of a member State**

**256F.**—(1) A person on the list must immediately inform the competent authority of a member State and, where applicable, the marketing authorisation holder, of medicinal products which that person—

- (a) identifies as;
- (b) knows or suspects; or
- (c) has reasonable grounds for knowing or suspecting,

to be falsified.

(2) The person entered on the list must notify the competent authority of a member State of any change of circumstances which is material as regards that person's entry on the list.

(3) The competent authority of a member State may give a notice to a person on the list, requiring that person to provide information of a kind specified in the notice within the period specified in the notice.

(4) A notice under paragraph (3) may not be given to a person on the list unless it appears to the competent authority of a member State that it is necessary for that competent authority to consider whether that person's entry on the list should be varied, suspended or removed.

(5) A notice under paragraph (4) may specify information which the competent authority of a member State thinks necessary for considering whether the person's entry on the list should be varied, suspended or removed.

#### **Grant or refusal to list a person**

**256G.**—(1) On receipt of a notification from a person to be included in the list—

- (a) the competent authority of a member State must include that person on the list if that person complies with the requirements in regulation 256C(2) to (5); or
- (b) if it considers necessary or appropriate to do so, the competent authority of a member State must refuse to include that person on the list having had regard to—
  - (i) the provisions of these Regulations, and
  - (ii) any EU obligation.

(2) The competent authority of a member State must give a notice stating the reasons for its decision in any case where that competent authority—

- (a) refuses to include a person on the list; or
- (b) includes a person in the list otherwise than in accordance with the notification and that person requests a statement of its reasons.

(3) Where the competent authority of a member State decides to include a person on the list that competent authority must ensure that the relevant website of the member State includes—

- (a) the name or corporate name of the person that is listed; and
- (b) the person's website address in the United Kingdom.

#### **Conditions to be met by a person entered on the list**

**256H.**—(1) A person entered on the list shall not sell a medicinal product at a distance by information society services unless the following conditions are satisfied.

(2) Condition A is that the person entered on the list must comply with regulation 256B.

(3) Condition B is that without prejudice to the information requirements set out in Directive 2000/31/EC(28) of the European Parliament and of the Council on certain legal aspects of information society services, in particular electronic commerce, in the Internal

Market, (Directive on electronic commerce), the website used to sell medicinal products at a distance must contain—

- (a) the contact details of the competent authority of a member State which is responsible for maintaining the list on which the person selling products at a distance is included;
- (b) a hyperlink to the relevant website of the Member State.

(4) Condition C is that without prejudice to any implementing Acts adopted by the Commission under Article 85c(3) of the 2001 Directive<sup>(29)</sup> the website used to sell medicinal products at a distance must contain the common logo which—

- (a) is clearly displayed on every page of the listed person's website that relates to medicinal products offered for sale at a distance; and
- (b) contains a hyperlink to the entry of that person in the list.

#### **Power to suspend, vary or remove a person's entry on the list**

**256I.**—(1) The competent authority of a member State may in accordance with regulation 256J—

- (a) suspend a person's entry on the list for such period as the authority thinks fit;
- (b) vary a person's entry on the list; or
- (c) remove a person's entry from the list.

(2) The suspension of person from the list may be—

- (a) total;
- (b) limited to medicinal products of one or more descriptions; or
- (c) limited to medicinal products sold at a distance from specified premises or a specified part of any premises.

(3) The power conferred by this regulation may only be exercised on one or more of the following grounds—

- (a) in relation to any information notified to the competent authority of a member State under regulation 256C as a result of which the person was included in the list—
  - (i) the information so supplied was false or incomplete in a material respect,
  - (ii) a material change of circumstances has occurred in relation to any of the matters stated in the notification;
- (b) the person on the list has materially contravened a condition required to be met by a person entered on the list under regulation 256H; or
- (c) the person on the list has without reasonable excuse failed to supply information to the competent authority of a member State with respect to their notification when required to do so under regulation 256F(3).

#### **Procedure where the competent authority of a member State proposes to suspend, vary or remove a person's entry on the list**

**256J.**—(1) This regulation applies where—

- (a) the provisions of regulation 256K do not apply; and

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<sup>(29)</sup> Article 85c was inserted into Directive 2001/83/EC by Directive 2011/62/EU of the European Parliament and of the Council (OJ No L 174, 1.7.2011, p74).



- (b) the competent authority of a member State proposes to exercise the power in regulation 256I.
- (2) The competent authority of a member State must notify the person on the list in writing of—
  - (a) its proposal;
  - (b) the reasons for it; and
  - (c) a specified date on which it is proposed that the suspension, variation or revocation should take effect.
- (3) The specified date in paragraph (2)(c) must be no earlier than 28 days following the date of the notice given by the competent authority of a member State.
- (4) The person to whom notice is given under paragraph (2) may before the date specified in the notice—
  - (a) make written representations to the competent authority of a member State with respect to the proposal; or
  - (b) notify the competent authority of a member State that the person wishes that competent authority to submit the proposal to review upon oral representations.
- (5) If person on the list makes written representations in accordance with subparagraph (4)(a) the competent authority of a member State must take those representations into account before making a decision in the matter.
- (6) If the person on the list gives notice of the proposal to review upon oral representation in accordance with paragraph (4)(b)—
  - (a) Schedule 5 has effect; and
  - (b) any reference to the licensing authority in Schedule 5 shall be read as a reference to the competent authority of a member State.
- (7) If the competent authority of a member State proceeds to suspend, vary or remove a person's entry on the list in accordance with the provisions of regulation 256I it must give a notice to that person.
- (8) The notice must—
  - (a) give particulars of the suspension, variation or removal; and
  - (b) give reasons for the decision to suspend, vary or remove the person's entry on the list.
- (9) Paragraphs (7) and (8) are without prejudice to any requirement of Schedule 5 as to notification.

**Suspension of a person's entry on the list in cases of urgency**

- 256K.**—(1) The competent authority of a member State may immediately suspend a person's entry on the list for a period not exceeding three months where it appears to that competent authority that in the interests of safety it is appropriate to do so.
- (2) This paragraph applies where—
    - (a) a person's entry on the list has been suspended under paragraph (1); and
    - (b) it appears to the competent authority of a member State that it is necessary to consider whether the person's entry on the list should be—
      - (i) further suspended or varied, or
      - (ii) removed from the list.

(3) Where paragraph (2) applies, the competent authority of a member State must proceed as set out in regulation 256I (but this is subject to paragraph (4)).

(4) Paragraph (5) applies where, in circumstances where paragraph (2) applies, the competent authority of a member State proceeds as set out in regulation 256I and any proceedings under that regulation have not been finally disposed of before the end of the period for which the person's entry was suspended under paragraph (1) or further suspended under paragraph (5).

(5) If it appears to the competent authority of a member State to be necessary in the interests of safety to do so, the authority may further suspend the person's entry on the list for a period which (in the case of each further suspension) is not to exceed three months.

(6) In the event that any challenge against a decision under regulation 256I to suspend, vary or remove a person's entry on the list is made on an application under regulation 322(4) (validity of decisions and proceedings), paragraph (5) shall apply, but this is without prejudice to regulation 322(6)(a) (interim order of the High Court).

#### **Variation of a person's entry on the list on the application of that person**

**256L.**—(1) This regulation applies if a person entered on the list applies to the competent authority of a member State for a variation of the person's entry on the list.

(2) The application must—

- (a) be in writing;
- (b) specify the variation requested;
- (c) be signed by or on behalf of the applicant; and
- (d) be accompanied by such information as may be required to enable the competent authority of a member State to consider the application.

(3) The competent authority of a member State must vary a person's entry on the list or refuse to vary it within 30 days beginning with the day after the date when that competent authority receives the application.

(4) The competent authority of a member State may give a notice to the applicant requiring the applicant to supply further information in connection with the application within the period specified in the notice.

(5) If a notice under paragraph (4) requires the applicant to provide the competent authority of a member State with information, the information period is not to be counted for the purposes of paragraph (3).

(6) In paragraph (5), the "information period" means the period—

- (a) beginning with the day on which notice under paragraph (4) is given; and
- (b) ending with the day on which the competent authority of a member State receives the information or the applicant shows to that competent authority's satisfaction that the applicant is unable to provide it.

(7) Nothing in this regulation affects the powers conferred by regulations 256I and 256K.

#### **Offences: breach of regulations and false information**

**256M.**—(1) A person is guilty of an offence if the person—

- (a) contravenes regulation 256B(1); or
- (b) offers medicinal products for sale at a distance otherwise than in accordance with the conditions in regulation 256H.

- (2) A person is guilty of an offence if the person knowingly gives false information in—
- (a) an application to be entered on the list in accordance with regulation 256C(2);
  - (b) an application for a variation in accordance with regulation 256L(2); or
  - (c) response to a notice under regulation 256L(4).
- (3) A person is guilty of an offence if, without reasonable excuse, the person fails to comply with a notice under regulation 256F(3) or 256L(4).
- (4) A person is guilty of an offence if that person fails to inform the competent authority of a member State—
- (a) of a falsified medicinal product in accordance with regulation 256F(1); or
  - (b) about a material change of circumstances in accordance with regulation 256F(2).
- (5) It is a defence for a person charged with an offence under paragraph (4) to show that the person exercised all due diligence to avoid committing the offence.

### Penalties

- 256N.**—(1) A person guilty of an offence under regulation 256M(1), (2) or (4) is liable—
- (a) on summary conviction to a fine not exceeding the statutory maximum; or
  - (b) on conviction on indictment to a fine, to imprisonment for a term not exceeding two years, or to both.
- (2) A person guilty of an offence under regulation 256M(3) is liable on summary conviction to a fine not exceeding level 3 on the standard scale.”

### Substitution of regulation 327

- 29.**—(1) Regulation 327 (powers of inspection, sampling and seizure) is amended as follows.
- (2) For paragraph (4)(c) substitute—
- “(c) in relation to an application under Parts 3 or 5 to 8 in order to verify any statement made by an applicant for—
- (i) a manufacturer’s licence,
  - (ii) a wholesale dealer’s licence,
  - (iii) a brokering registration,
  - (iv) registration as an importer, manufacturer or distributor of active substances,
  - (v) a marketing authorisation,
  - (vi) a certificate of registration,
  - (vii) a traditional herbal registration, or
  - (viii) an Article 126a authorisation;
- (d) in relation to a person’s notification to sell medicinal products at a distance under Part 12A.”
- (3) For paragraphs (2) to (4) substitute—
- “(2) The things mentioned in paragraph (1) are—
- (a) a substance or article appearing to the inspector to be a medicinal product or an active substance;
  - (b) an article appearing to the inspector to be—

- (i) a container or package used or intended to be used to contain a medicinal product or an active substance, or
- (ii) a label or leaflet used or intended to be used in connection with a medicinal product or an active substance;
- (c) plant or equipment, including computer equipment, appearing to the inspector to be used or intended to be used in connection with the manufacture, assembly, importation, sale, supply or advertising of, or wholesale dealing in, medicinal products or active substances;
- (d) any process of manufacture or assembly of medicinal products or active substances;
- (e) the way in which medicinal products or active substances, or the materials used in the manufacture of medicinal products or active substances, are tested at any stage in the process of manufacture or assembly;
- (f) information and documents relating to the manufacture, assembly, importation, sale, supply or advertising of, or wholesale dealing in, medicinal products or active substances;
- (g) information and documents relating to the safety of medicinal products or active substances, including information and documents relating to compliance with—
  - (i) conditions imposed under any of regulations 59 (conditions of UK marketing authorisation: general), 60 (conditions of UK marketing authorisation: exceptional circumstances), 61 (conditions of UK marketing authorisation: new obligations post-authorisation) or 105 (conditions of certificate of registration),
  - (ii) the requirements of Part 11 (pharmacovigilance),
  - (iii) obligations and conditions under Articles 10a(1), 14(7), 14(8), 16 or 57(2) of Regulation [\(EC\) No 726/2004](#),
  - (iv) the requirements of Chapter 3 (pharmacovigilance) of Title II of Regulation [\(EC\) No 726/2004](#),
  - (v) the requirements of the Implementing Regulation as defined in regulation 177(5) (pharmacovigilance: interpreting provision), and
  - (vi) obligations under regulations 75 (obligation to provide information relating to safety) and 76 (obligation in relation to product information).
- (3) The inspector may for the purposes specified in paragraph (1) take or purchase a sample of a substance or article which appears to the inspector to be—
  - (a) a medicinal product or an active substance which is, or is intended to be, sold or supplied; or
  - (b) a substance or article used, or intended to be used, in the manufacture of a medicinal product or an active substance.
- (4) The inspector may for the purposes specified in paragraph (1) require a person carrying on a business which consists of or includes the manufacture, assembly, importation, sale, supply or advertising of, or wholesale dealing in, medicinal products or active substances, or a person employed in connection with such a business, to produce information or documents relating to the business which are in the person's possession or under the person's control.”
- (4) For paragraph (6) substitute—

“(6) The inspector may seize and retain a substance or article appearing to the inspector to be a medicinal product or an active substance if the inspector reasonably believes that an offence under these Regulations is being or has been committed in relation to, or by means of, that substance or article.”

### **Amendment of regulation 330**

**30.** In regulation 330 (analysis of samples: other cases), for paragraphs (1) and (2) substitute—

“(1) This regulation applies where a person other than an inspector or a person authorised by an enforcement authority has purchased an active substance or a medicinal product.

(2) The person may submit a sample of the active substance or medicinal product for analysis to the public analyst for the area in which the active substance or medicinal product was purchased or, if for the time being there is no public analyst for the area, to the public analyst for another area.”

### **Substitution of regulation 346**

**31.** For regulation 346 (review) substitute—

#### **“Review**

**346.**—(1) The Secretary of State must from time to time carry out a review of the provisions listed in paragraph (2).

(2) Those provisions are—

- (a) Chapters 1, 3 and 4 of Part 3;
- (b) Parts 11 and 12A;
- (c) regulations—
  - (i) 18(6)(a),
  - (ii) 20(1),
  - (iii) 37(4)(b), (5), (6), (11) and (12),
  - (iv) 43(5), (6)(a), 7(c)(iii) and (vii), (8) and (10) to (14),
  - (v) 44(1) to (6),
  - (vi) 59,
  - (vii) 60(3)(b), (9) and (10),
  - (viii) 61,
  - (ix) 63,
  - (x) 64(4)(b), (d) and (e), (5)(a) and (6)(c),
  - (xi) 65(2),
  - (xii) 66(5) and (6),
  - (xiii) 68(2)(a) and (b), (5) and (12A),
  - (xiv) 69(2)(a) and (b), (5) and (10),
  - (xv) 75(2)(b) and (c),
  - (xvi) 76,
  - (xvii) 79,
  - (xviii) 85,

- (xix) 86,
- (xx) 97,
- (xxi) 105(3)(b),
- (xxii) 107(2),
- (xxiii) 108(5),
- (xxiv) 110(8A),
- (xxv) 115(2)(b) and (c),
- (xxvi) 132(2),
- (xxvii) 133(5) and (6),
- (xxviii) 135(10A),
- (xxix) 266(4) and (5),
- (xxx) 327(2)(g) and insofar as the provision relates to active substances paragraphs (1)(c)(iii), (iv) and (viii), (2)(a) to (f), (3), (4) and (6),
- (xxxi) 330(1) and (2),
- (xxxii) 331, and
- (xxxiii) regulation 349 insofar as it repeals section 10(7) of the Medicines Act 1968;  
and
- (d) Schedules—
  - (i) 5 paragraphs 1(1)(b) to (d), (2)(b) to (d), 3(11)(b)(vi) to (viii), 5(2)(f) to (h),
  - (ii) 7A,
  - (iii) 8 paragraphs 9A, 12, 13, 19 and 23,
  - (iv) 12 paragraph 21, and
  - (v) 27 paragraphs 14 and 15.
- (3) The Secretary of State must—
  - (a) set out the conclusions of a review carried out in accordance with paragraph (1) in a report; and
  - (b) publish the report.
- (4) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how the 2001 Directive, Directive 2010/84/EU(30) and Directive 2011/62/EU(31) are implemented in other member States in relation to the subject matter of the provisions mentioned in paragraph (2).
- (5) The report must in particular—
  - (a) set out the objectives intended to be achieved by the regulatory system established by the provisions of these Regulations that implement those Directives in relation to the subject matter of the provisions mentioned in paragraph (2)(a), (b), (c)(i) to (xxix) and (d);
  - (b) assess the extent to which those objectives are achieved; and
  - (c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

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(30) Directive 2010/84/EU of the European Parliament and of the Council (OJ No L 348, 31.12.2010, p74).

(31) Directive 2011/62/EU of the European Parliament and of the Council (OJ No L 174, 1.7.2011, p74).

(6) The first report under this regulation must be published before the end of the period of five years beginning with the day on which these Regulations come into force.

(7) Reports under this regulation are afterwards to be published at intervals not exceeding five years.”

### **Amendment of Schedule 5**

**32.** In Schedule 5 (review upon oral representations)—

(a) for paragraph 1 substitute—

“1.—(1) This Schedule applies if a person (“the applicant”) mentioned in sub-paragraph (2) notifies the licensing authority that the applicant wishes the licensing authority to submit the proposal or as the case may be the decision to review upon oral representations under—

- (a) regulation 27(3)(b);
- (b) regulation 45H(3)(b);
- (c) regulation 45R(3)(b);
- (d) regulation 256J(4)(b); or
- (e) Part 1, 2 or 3 of Schedule 11.

(2) Those persons are—

- (a) in respect of notification under regulation 27(3)(b) the licence holder;
- (b) in respect of a notification under regulation 45H(3)(b) the person registered as a broker;
- (c) in respect of a notification under regulation 45R(3)(b) the person with an active substance registration;
- (d) in respect of a notification under regulation 256J(4)(b) the person on the list in accordance with Part 12A; and
- (e) in respect of a notification under Part 1, 2 or 3 of Schedule 11—
  - (i) an applicant for a UK marketing authorisation, certificate of registration or traditional herbal registration,
  - (ii) an applicant for the renewal of an authorisation, certificate or registration, and
  - (iii) the holder of an authorisation, certificate or registration.”:

(b) in paragraph 3(11)(b)—

- (i) in paragraph (iv) omit “or”;
- (ii) before the closing words “as the case may be” insert—
  - “(vi) to proceed to suspend, vary or remove the person’s broker registration,
  - (vii) to proceed to suspend, vary or remove the person’s active substance registration, or
  - (viii) to proceed to suspend, vary or remove the person’s entry on the list,”; and

(c) in paragraph 5(2)—

- (i) in sub-paragraph (d) after “application;” omit “or”;
- (ii) for sub-paragraph (e) substitute—
  - “(e) to revoke, vary or suspend the authorisation, certificate or registration;

- (f) to proceed to suspend, vary or remove a person's broker registration;
- (g) to proceed to suspend, vary or remove a person's active substance registration; or
- (h) to proceed to suspend, vary or remove a person's entry on the list,".

### **Insertion of Schedule 7A**

33. Immediately after Schedule 7 (qualified persons) insert—

“SCHEDULE 7A

Regulation 45N(5)(b)

Information to be provided for registration as an  
importer, manufacturer or distributor of active substances

1. The name and address of the applicant.
2. The name and address of the person (if any) making the application on the applicant's behalf.
3. The address of each of the premises where any operations to which the registration relates are to be carried out.
4. The address of any premises not mentioned by virtue of the above requirement, where—
  - (a) the applicant proposes to keep any living animals, from which substance(s) used in the production of the active substance(s) to which the application relates are to be derived;
  - (b) materials of animal origin from which an active substance is to be derived, as mentioned in the above sub-paragraph, are to be kept.
5. The address of each of the premises where active substances are to be stored, or from which active substances are to be distributed.
6. The address of each of the premises where any testing associated with the manufacture or assembly of active substances to which the registration relates.
7. The name, address, qualifications and experience of the person whose duty it will be to supervise any manufacturing operations, and the name and job title of the person to whom they report.
8. The name, address, qualifications and experience of the person who will have responsibility for the quality control of active substances, and the name and job title of the person to whom they report.
9. The name, address, qualifications and experience of the person whose duty it will be to supervise any importation, storage or distribution operations, and the name and job title of the person to whom they report.
10. The name, address and qualifications of the person to be responsible for any animals kept as mentioned in paragraph 4(a).
11. The name, address and qualifications of the person to be responsible for the culture of any living tissue for use in the manufacture of an active substance.
12. For each active substance to be manufactured, imported, or distributed—
  - (a) the CAS registration number(32) assigned to that active substance by the Chemical Abstracts Service, a division of the American Chemical Society;

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(32) Further information is available from the website of the Chemical Abstracts Service at [www.cas.org](http://www.cas.org).



- (b) where applicable, the Anatomical Therapeutic Category code(33) assigned to that active substance under the Anatomical Therapeutic Chemical Classification System used for the classification of drugs by the World Health Organisation's Collaborating Centre for Drug Statistics Methodology;
  - (c) either—
    - (i) the International Union of Pure and Applied Chemistry nomenclature, or
    - (ii) the common name; and
  - (d) the intended quantities of each active substance to be manufactured, imported or distributed.
- 13.** Details of the operations to which the registration relates, including a statement of whether they include—
- (a) the manufacture of active substances;
  - (b) the importation of active substances from third countries;
  - (c) the storage of active substances; or
  - (d) the distribution of active substances.
- 14.** A statement of the facilities and equipment available at each of the premises where active substances are to be manufactured, stored or distributed.
- 15.** A statement as to whether the particular active substances are intended for—
- (a) use in a medicinal product with an EU marketing authorisation;
  - (b) use in a special medicinal product; or
  - (c) export to a third country.
- 16.** A separate statement in respect of each of the premises mentioned in the application of—
- (a) the manufacturing, storage or distribution operations carried out at those sites, and the specific active substances to which those activities relate; and
  - (b) the equipment available at those premises for carrying out those activities.
- 17.** A statement of the authority conferred on the person responsible for quality control to reject unsatisfactory active substances.
- 18.** A description of the arrangements for the identification and storage of materials before and during the manufacture of active substances.
- 19.** A description of the arrangements for the identification and storage of active substances.
- 20.** A description of the arrangements at each of the premises where the applicant proposes to store active substances for ensuring, as far as practicable, the turn-over of stocks of active substances.
- 21.** A description of the arrangements for maintaining—
- (a) production records, including records of manufacture and assembly;
  - (b) records of analytical and other tests used in the course of manufacture or assembly for ensuring compliance of materials use in manufacture, or of active substances, with the specification for such materials or active substances;
  - (c) records of importation;
  - (d) records of storage and distribution.

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(33) Further information is available from the website of the WHO Collaborating Centre for Drug Statistics Methodology at [www.whocc.no](http://www.whocc.no).

22. A description of the arrangements for keeping reference samples of—

- (a) materials used in the manufacture of active substances; and
- (b) active substances.

23. Where the application relates to active substances intended for use in an advanced therapy medicinal product, an outline of the arrangements for maintaining records to allow traceability containing sufficient detail to enable the linking of an active substance to the advanced therapy medicinal product it was used in the manufacture of and vice versa.

24. Details of—

- (a) any manufacturing, importation, storage or distribution operations, other than those to which the application for registration relates, carried on by the applicant on or near each of the premises, and
- (b) the substances or articles to which those operations relate.”

#### **Amendment of Schedule 8**

34. In Schedule 8 (material to accompany an application for a UK marketing authorisation) after paragraph 9 insert—

“9A. A written confirmation that the manufacturer of the medicinal product has verified compliance of the manufacturer of the active substance with the principles and guidelines of good manufacturing practice by conducting audits, in accordance with regulation 37(5) (a) and containing—

- (a) information about the date of the audit; and
- (b) a declaration that the outcome of the audit confirms that the manufacturing complies with the principles and guidelines of good manufacturing practice.”

## **PART 3**

### **Revocations**

#### **The Human Medicines Regulations 2012**

35. Regulation 32 (sale and supply of starting materials) of the Human Medicines Regulations 2012 is revoked.

Signed by authority of the Secretary of State for Health.

18th July 2013

22nd July 2013

*Earl Howe*  
Parliamentary Under-Secretary of State,  
Department of Health  
*Edwin Poots*  
Minister for Health, Social Services and Public  
Safety

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations amend the Human Medicines Regulations 2012 (“the 2012 Regulations”) in order to implement—

- Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive [2001/83/EC](#) on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products (“Directive 2011/62/EU”);
- Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation [\(EC\) No 726/2004](#) of the European Parliament and of the Council and Directive [2001/83/EC](#) of the European Parliament and of the Council (“the Implementing Regulation”);
- an EU Corrigendum<sup>(34)</sup> which corrects an error in Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicines for human use, Regulation [\(EC\) No 726/2004](#) laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation [\(EC\) No 1394/2007](#) on advanced therapy medicinal products (“the EU Corrigendum”).

The majority of provisions in these Regulations introduce new provisions into the 2012 Regulations in relation to brokers, active substances and the sale of medicinal products at a distance in order to implement Directive 2011/62/EU. In particular—

- regulation 3 updates the general interpretation provisions to insert new definitions;
- regulations 4 to 6, 9 to 15, 17, 19 and 20 amend provisions relating to manufacturers or wholesalers of medicinal products, marketing authorisations and traditional herbal registrations;
- regulation 16 inserts new provisions relating to brokers of medicinal products and importers, manufacturers or distributors of active substances;
- regulation 28 inserts new provisions relating to the sale at a distance of medicinal products;
- regulation 30, 34 and 35 make consequential amendments related active substances;
- regulation 32 amends provisions so that brokers of medicinal products and importers, manufacturers and distributors of active substances can apply for certain decisions to be reviewed upon oral representations; and
- regulation 33 inserts a new Schedule in relation to information requirements for registration in relation to active substances.

Regulations 21, 23 and 25 amend the 2012 Regulations in order to provide sanctions for breaches of obligations and requirements imposed by the Implementing Regulation in relation to pharmacovigilance activities and regulation 22 makes consequential changes to remove duplication of obligations.

Regulations 18 and 24 make amendments to ensure that cross-references to Regulation [\(EC\) No 726/2004](#) that were amended by the EU Corrigendum are correctly reflected in the 2012 Regulations.

<sup>(34)</sup> OJ No L 201, 27.7.2012, p138.

Regulations 7, 26 and 27 insert new provisions into the 2012 Regulations that enable physiotherapist independent prescribers and podiatrist independent prescribers to mix, sell or supply certain types of prescription only medicines.

Regulation 8 amends the 2012 Regulations so that where a licence holder wishes to make oral representations to the licensing authority a fee is payable by the licence holder.

Regulations 29 and 31 amend the 2012 Regulations to ensure that regulations related to inspections, sampling and seizure and the review of provisions can be applied in relation to new provisions for brokers, the importation, manufacture and distribution of active substances and the sale of medicines to the public at a distance.