STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 3

Manufacturing and wholesale dealing

Grant etc of licences

Manufacturing of medicinal products

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

(a) manufacture, assemble or import from a state other than an EEA State any medicinal product; or

(b) possess a medicinal product for the purpose of any activity in sub-paragraph (a).

(2) Paragraph (1) is subject to paragraphs (3) to (5).

(3) Paragraph (1) applies in relation to 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 or assembly of the product is in accordance with the terms and conditions of that authorisation, certificate or registration.

(4) In paragraph (3), "marketing authorisation" means—

(a) a marketing authorisation issued by a competent authority in accordance with the 2001 Directive; or

(b) an EU marketing authorisation.

(5) Paragraph (1) does not apply to a person who, in connection with the importation of a medicinal product from a state other than an EEA State—

(a) provides facilities solely for transporting the product; or

(b) acting as an import agent, imports the medicinal product solely to the order of another person who holds a manufacturer's licence authorising the importation of the product.

(6) Paragraph (1) does not apply to a person who imports a medicinal product for administration to himself or herself or to any other person who is a member of that person's household.

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) is subject to paragraphs (4) to (6) and 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 specified in the licence.

(4) Paragraph (1) does not apply to anything done in relation to a medicinal product by the holder of a manufacturer's licence in respect of that product.

(5) Paragraph (1) does not apply where the product concerned is an investigational medicinal product.

(6) Paragraph (1) does not apply if the product is a radiopharmaceutical in which the radionuclide is in the form of a sealed source.

(7) 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 to another EEA State for the purposes of sale or supply,

to a person who receives it for a purpose within paragraph (8).

(8) 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.

(9) 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 is subject to the exceptions in regulation 43(6)).

(10) In paragraph (9), "marketing authorisation" means—

(a) a marketing authorisation issued by a competent authority in accordance with the 2001 Directive; or

(b) an EU marketing authorisation.

Exemptions from requirement for wholesale dealer's licence

19.—(1) Regulation 18 does not apply to the sale or offer for sale of a medicinal product by way of wholesale dealing, or possession for the purpose of such sale or offer, where paragraph (2) applies and the person selling or offering the product for sale is—

(a) the holder of a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration, (an "authorisation") which relates to the product, including a holder of an authorisation who manufactured or assembled the product; or

(b) a person who is not the holder of an authorisation in relation to the product but manufactured or assembled the product to the order of a person who is the holder of an authorisation relating to the product.

(2) This paragraph applies if—

(a) until the sale, the medicinal product has been kept on the premises of the person who manufactured or assembled the product (in this regulation referred to as "authorised premises"); and

(b) those premises are premises authorised for use for manufacture or assembly by that person's manufacturer's licence.

(3) For the purposes of this regulation, a medicinal product is regarded as having been kept on authorised premises at a time when—

(a) it was being moved from one set of authorised premises to another, or from one part of authorised premises to another part; or

(b) it was being moved from authorised premises by way of delivery to a purchaser.

(4) Regulation 18 does not apply to a person who in connection with the importation of a medicinal product—

(a) provides facilities solely for transporting the product; or

(b) acting as an import agent, handles the product where the product is imported solely to the order of another person who intends to sell the product or offer it for sale by way of wholesale dealing or to distribute it in any other way.

(5) Regulation 18 does not apply to the distribution of a medicinal product by way of wholesale dealing, or to the possession of a medicinal product for the purpose of such distribution, if the distribution or possession is solely for the purpose of exporting the product to states other than EEA States.

Mixing of medicines

20.—(1) Regulation 17(1) (manufacturing of medicinal products) does not apply to the mixing of medicines by—

(a) a nurse independent prescriber;

(b) a pharmacist independent prescriber;

(c) a supplementary prescriber, if the mixing of medicines forms part of the clinical management plan for an individual patient;

(d) a person acting in accordance with the written directions of a—

(i) doctor,

(ii) dentist,

(iii) nurse independent prescriber, or

(iv) pharmacist independent prescriber; or

(e) a person acting in accordance with the written directions of a supplementary prescriber, if the mixing of medicines forms part of the clinical management plan for an individual patient.

(2) In this regulation "mixing of medicines" means the combining of two or more medicinal products together for the purposes of administering them to meet the needs of an individual patient.

Application for manufacturer's or wholesale dealer's licence

21.—(1) An application for a grant of a licence under this Part must—

(a) be made to the licensing authority;

(b) be made in the way and form specified in Schedule 3; and

(c) contain or be accompanied by the information, documents, samples and other material specified in that Schedule.

(2) An application must indicate the descriptions of medicinal products in respect of which the licence is required, either by specifying the descriptions of medicinal products in question or by way of an appropriate general classification.

Factors relevant to determination of application for manufacturer's or wholesale dealer's licence

22.—(1) In dealing with an application for a manufacturer's licence the licensing authority must in particular take into consideration—

(a) the operations proposed to be carried out under the licence;

(b) the premises in which those operations are to be carried out;

(c) the equipment which is or will be available on those premises for carrying out those operations;

(d) the qualifications of the persons under whose supervision the operations will be carried out; and

(e) the arrangements made or to be made for securing the safekeeping of, and the maintenance of adequate records in respect of, medicinal products manufactured or assembled in pursuance of the licence.

(2) In dealing with an application for a wholesale dealer's licence the licensing authority must in particular take into consideration—

(a) the premises on which medicinal products of the descriptions to which the application relates will be stored;

(b) the equipment which is or will be available for storing medicinal products on those premises;

(c) the equipment and facilities which are or will be available for distributing medicinal products from those premises; and

(d) the arrangements made or to be made for securing the safekeeping of, and the maintenance of adequate records in respect of, medicinal products stored on or distributed from those premises.

Grant or refusal of licence

23.—(1) Subject to the following provisions of these Regulations, on an application to the licensing authority for a licence under this Part the licensing authority may—

(a) grant a licence containing such provisions as it considers appropriate; or

(b) refuse to grant a licence if having regard to the provisions of these Regulations and any European Union obligation it considers it necessary or appropriate to do so.

(2) The licensing authority must grant or refuse an application for a licence under this Part within the period of 90 days beginning immediately after the day on which it receives the application.

(3) Paragraph (2) applies to an application only if the requirements of Schedule 3 have been met.

(4) If a notice under regulation 30 requires the applicant to provide the licensing authority with information, the information period is not to be counted for the purposes of paragraph (2).

(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.

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

(a) the licensing authority refuses to grant an application for a licence; or

(b) the licensing authority grants a licence otherwise than in accordance with the application and the applicant requests a statement of its reasons.

Standard provisions of licences

24.—(1) The standard provisions set out in Schedule 4 may be incorporated by the licensing authority in a licence under this Part granted on or after the date on which these Regulations come into force.

(2) The standard provisions may be incorporated in a licence with or without modifications and either generally or in relation to medicinal products of a particular class.

Duration of licence

25. A licence granted under this Part remains in force until—

(a) the licence is revoked by the licensing authority; or

(b) the licence is surrendered by the holder.

General power to suspend, revoke or vary licences

26.—(1) The licensing authority may in accordance with the procedure specified in regulation 27—

(a) suspend a licence under this Part for such period as the authority thinks fit;

(b) revoke a licence under this Part; or

(c) vary the provisions of a licence under this Part.

(2) The suspension or revocation of a licence 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 manufacturer's licence or a wholesale dealer's licence except on one or more of the grounds specified in—

(a) paragraph (4) (in relation to either a manufacturer's licence or a wholesale dealer's licence);

(b) paragraph (5) (in relation to a manufacturer's licence); or

(c) paragraph (6) (in relation to a wholesale dealer's licence).

(4) Those grounds are that—

(a) the information in the application as a result of which the licence 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 holder of the licence has materially contravened a provision of it; or

(d) the holder of the licence has without reasonable excuse failed to supply information to the licensing authority with respect to medicinal products of a description to which the licence relates when required to do so under regulation 30(2).

(5) In relation to a manufacturer's licence, the powers conferred by this regulation may also be exercised on either or both of the following grounds—

(a) that the holder of the manufacturer's licence has manufactured or assembled medicinal products to the order of a person who holds a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration (an "authorisation") and has habitually failed to comply with the provisions of that authorisation; or

(b) that the holder of the manufacturer's licence does not have appropriate facilities to carry out processes of manufacture or assembly authorised by the licence.

(6) In relation to a wholesale dealer's licence, the powers conferred by this regulation may also be exercised on the grounds that the equipment and facilities available to the holder of the licence for storing or distributing medicinal products are inadequate to maintain the quality of medicinal products of one or more descriptions to which the licence relates.

Procedure where licensing authority proposes to suspend, revoke or vary licence

27.—(1) This regulation applies where—

(a) the provisions of regulation 28 do not apply; and

(b) the licensing authority proposes to suspend, vary or revoke a licence under regulation 26.

(2) The licensing authority must notify the licence holder 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, revocation or variation should take effect.

(3) The licence holder 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 holder wishes the licensing authority to submit the proposal to review upon oral representations.

(4) If the licence holder 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) 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), Schedule 5 has effect.

(6) If the licensing authority proceeds to suspend, revoke or vary a licence in accordance with the provisions of regulation 26 it must give a notice to the licence holder.

(7) The notice must—

(a) give particulars of the suspension, revocation or variation; and

(b) give reasons for the decision to suspend, revoke or vary the licence.

(8) Paragraphs (6) and (7) are without prejudice to any requirement of Schedule 5 as to notification.

Suspension of licence in cases of urgency

28.—(1) Notwithstanding anything in the preceding provisions of this Part, where it appears to the licensing authority that in the interests of safety it is necessary to suspend a licence under this Part with immediate effect, the licensing authority may do so for a period not exceeding three months.

(2) This paragraph applies where—

(a) a licence has been suspended under paragraph (1); and

(b) it appears to the licensing authority that it is necessary to consider whether the licence should be further suspended, revoked or varied.

(3) Where paragraph (2) applies, the licensing authority must proceed as set out in regulation 27 (but this is subject to paragraphs (4) and (5)).

(4) Paragraph (5) applies where, in circumstances where paragraph (2) applies, the licensing authority proceeds as set out in regulation 27 and any proceedings under that regulation have not been finally disposed of before the end of the period for which the licence 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 licence 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 27 to suspend, vary or revoke the licence 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).

Variation of licence on the application of the holder

29.—(1) This regulation applies if the holder of a licence under this Part applies to the licensing authority for a variation of the licence.

(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) be accompanied by the required fee (if any).

(3) The licensing authority must consider an application made in accordance with this regulation.

(4) If paragraph (5) applies, the licensing authority must vary the licence or refuse to vary it before the end of the period allowed for considering the application.

(5) This paragraph applies to a variation which would have the effect of altering—

(a) the types of medicinal product in respect of which the licence was granted;

(b) any operation carried out under the licence; or

(c) any premises, equipment or facilities in respect of which the licence was granted.

(6) The period allowed for consideration of an application under this regulation is—

(a) in a case where the licensing authority considers that it is necessary to inspect premises to which the licence relates, 90 days beginning with the day after the date when the licensing authority receives the application; and

(b) in any other case 30 days beginning with that day.

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

(8) If a notice under paragraph (7) requires the applicant to provide the licensing authority with information, the information period is not to be counted for the purposes of paragraph (6).

(9) In paragraph (8), 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.

(10) Nothing in this regulation affects the powers conferred by regulation 26.

Provision of information

30.—(1) Where an application has been made to the licensing authority for a licence under this Part, the licensing authority may, before determining the application, require the applicant to provide such information as the licensing authority thinks necessary, within the period specified by the licensing authority.

(2) The licensing authority may give a notice to the holder of a licence under this Part, requiring the holder to provide information of a kind specified in the notice within the period specified in the notice.

(3) A notice under paragraph (2) may not be given to the holder of a licence unless it appears to the licensing authority, or representations are made to the licensing authority by the Commission, an expert advisory group of the Commission, or an expert committee appointed by the licensing authority, that it is necessary for the licensing authority to consider whether the licence should be varied, suspended or revoked.

(4) A notice under paragraph (2) may specify information which the licensing authority, or the Commission, an expert advisory group of the Commission, or an expert committee appointed by the licensing authority, thinks necessary for considering whether the notice should be varied, suspended or revoked.

Miscellaneous and offences

Certification of manufacturer's licence

31.—(1) The licensing authority must issue a certificate in accordance with the following paragraphs of this regulation in relation to a manufacturer's licence relating to the manufacture or assembly of medicinal products if requested to do so by—

(a) subject to paragraph (5), the holder of the licence;

(b) a person who intends to export a medicinal product manufactured or assembled by the holder under the licence; or

(c) the competent authorities of a country other than an EEA State into which a medicinal product manufactured or assembled under the licence is, or is proposed to be, imported.

(2) The certificate must contain —

(a) information sufficient to identify the holder of the manufacturer's licence;

(b) details of the medicinal products that may be manufactured or assembled under the licence; and

(c) any other information concerning the holder, the product or the licence that the licensing authority thinks it appropriate to include, including information relating to clinical trials.

(3) If—

(a) a request is made—

(i) under paragraph (1)(a) in relation to the export or the proposed export of a product, or

(ii) under paragraph (1)(b) or (c); and

(b) there is a marketing authorisation or a traditional herbal registration in force for any product to which the licence relates,

the certificate must be accompanied by the summary of the product characteristics relating to that product.

(4) The licensing authority may restrict the information provided under sub-paragraphs (2)(a) and (b) and paragraph (3) to information relating to the specific medicinal products mentioned in the request made under paragraph (1).

(5) A licence holder who makes a request under paragraph (1) must—

(a) produce to the licensing authority a marketing authorisation, certificate of registration or traditional herbal registration in relation to any product to which the certificate is to relate; or

(b) make a declaration to the licensing authority explaining why no marketing authorisation, certificate of registration or traditional herbal registration is available.

(6) The licensing authority must have regard to the prevailing administrative arrangements of the World Health Organisation when issuing the certificate.

Sale and supply of starting materials

32. A person must not sell or supply an active substance if the active substance—

(a) has not been manufactured or assembled in accordance with the principles and guidelines for good manufacturing practice applicable to starting materials and set out in the Good Manufacturing Practice Directive; and

(b) is sold or supplied to a person for use in the manufacture of a medicinal product, except where—

(i) the product is a special medicinal product, or

(ii) regulation 17(1) (manufacturing of medicinal products) does not apply to the manufacture of the product by virtue of any provision of section 10 of the Medicines Act 1968.

Offence concerning data for advanced therapy medicinal products

33.—(1) A person who is, or immediately before its revocation or suspension was, the holder of a manufacturer's licence relating to an advanced therapy medicinal product is guilty of an offence if the person fails to—

(a) keep the data referred to in Article 15(1) of Regulation (EC) No 1394/2007 in accordance with the requirements of Article 15(4) of that Regulation; or

(b) transfer the data referred to in Article 15(1) to the licensing authority in the event of that person's bankruptcy or liquidation,

but this is subject to paragraphs (2) and (3).

(2) Sub-paragraph (1)(b) does not apply if—

(a) the person is bankrupt or in liquidation and has transferred the data to another person; or

(b) the period for which the person was required to keep the data in accordance with the requirements of Article 15(4) mentioned in sub-paragraph (1)(a) has expired.

(3) It is a defence for a person charged with an offence under paragraph (1) to prove that the person took all reasonable precautions and exercised all due diligence to avoid commission of the offence.

(4) Where evidence is adduced that is sufficient to raise an issue with respect to the defence in paragraph (3), the court or jury must presume that the defence is satisfied unless the prosecution proves beyond reasonable doubt that it is not.

Offences: breach of regulations and false information and defence concerning starting materials

34.—(1) A person is guilty of an offence if the person contravenes the provisions of regulation 17(1), 18(1) or 32.

(2) A person is guilty of an offence if the person knowingly gives false information in response to a notice under regulation 30(1).

(3) A person is guilty of an offence if, without reasonable excuse, the person fails to comply with a notice under regulation 30(2).

(4) The defence in paragraph (5) applies to a person who is charged under paragraph (1) with an offence of contravening regulation 17(1) (prohibition on manufacturing a medicinal product except in accordance with a licence) by virtue of a breach of regulation 37(2)(b) (requirement that active substances used as starting materials are manufactured or assembled in accordance with the Good Manufacturing Practice Directive).

(5) It is a defence for the person to show that the person could not, by taking all reasonable precautions and exercising all due diligence, have discovered that an active substance was not manufactured in accordance with regulation 37(2)(b).

Penalties

35.—(1) A person guilty of an offence under regulation 33(1) or regulation 34(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 34(3) is liable on summary conviction to a fine not exceeding level 3 on the standard scale.

Conditions for holding a manufacturer's licence

Conditions for manufacturer's licence

36.—(1) Regulations 37 to 41 apply to the holder of a manufacturer's licence (referred to in those regulations as "the licence holder") and have effect as if they were provisions of the licence (but the provisions specified in paragraph (2) do not apply to the holder of a manufacturer's licence insofar as the licence relates to the manufacture or assembly of exempt advanced therapy medicinal products).

(2) Those provisions are regulations 37(2)(b), 38, 39(6)(a) and (8) , 40 and 41.

(3) The requirements of Part 1 of Schedule 6 apply to the holder of a manufacturer's licence insofar as the licence relates to the manufacture or assembly of exempt advanced therapy medicinal products, and have effect as if they were provisions of the licence.

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—

(a) comply with the principles and guidelines for good manufacturing practice set out in the Good Manufacturing Practice Directive; and

(b) use active substances as starting materials only if those substances have been manufactured or assembled in accordance with the principles and guidelines mentioned in paragraph (a), in so far as those principles and guidelines relate to starting materials (but see paragraph (3)).

(3) The requirement in paragraph (2)(b) does not apply in relation to the manufacture or assembly of special medicinal products.

(4) 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.

(5) The licence holder must not manufacture or assemble medicinal products, or classes of medicinal products, other than those specified in the licence.

(6) 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.

(7) 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(**1**); or

(b) equivalent standards.

Imports from states other than EEA States

38.—(1) This regulation applies in relation to a manufacturer's licence relating to the import of medicinal products.

(2) The licence holder must comply with the conditions set out in this regulation in relation to the import of medicinal products from a state other than an EEA State.

(3) The licence holder must—

(a) comply with the principles and guidelines on good manufacturing practice in the Good Manufacturing Practice Directive in so far as they are relevant to the import of medicinal products; and

(b) ensure that active substances have been used as starting materials in the manufacture of medicinal products, other than special medicinal products, imported from a state other than an EEA State only if those substances have been manufactured or assembled in accordance with the principles and guidelines mentioned in paragraph (a), in so far as those principles and guidelines relate to starting materials.

Further requirements for manufacturer's licence

39.—(1) This regulation applies in relation to any manufacturer's licence.

(**1**) OJ L 91, 30.3.2004, p.25.

(2) The licence holder must maintain such staff, premises, equipment and facilities for the handling, control, storage and distribution of medicinal products under the licence as are appropriate in order to maintain the quality of the medicinal products.

(3) The licence holder must ensure that any arrangements made for the handling, control, storage and distribution of medicinal products are adequate to maintain the quality of the products.

(4) The licence holder must not handle, control, store or distribute medicinal products on any premises other than those specified in the licence as approved by the licensing authority for the purpose.

(5) The licence holder must inform the licensing authority before making a material alteration to the premises or facilities used under the licence, or to the purposes for which those premises or facilities are used.

(6) The licence holder must inform the licensing authority of any proposed change to—

(a) the qualified person; and

(b) any person named in the licence as having responsibility for quality control.

(7) For the purposes of enabling the licensing authority to determine whether there are grounds for suspending, revoking or varying the licence, the licence holder must permit a person authorised in writing by the licensing authority to do anything that the licensing authority could have done for the purposes of verifying a statement made in an application for a licence.

(8) In distributing a medicinal product by way of wholesale dealing, the licence holder must comply with regulations 43(1), (2) and (5) and 44(2) and (3) as if the licence holder were the holder of a wholesale dealer's licence.

Obligation to provide information relating to control methods

40.—(1) This regulation applies in relation to any manufacturer's licence.

(2) The licensing authority may require the licence holder to provide the authority with proof of the control methods employed by the holder in relation to a medicinal product.

Requirements as to qualified persons

41.—(1) This regulation applies in relation to any manufacturer's licence.

(2) The licence holder must ensure that there is at the disposal of the holder at all times at least one qualified person who is responsible for carrying out, in relation to medicinal products manufactured, assembled or imported under the licence, the duties specified in Part 3 of Schedule 7.

(3) If the licence holder satisfies the requirements of Part 1 or 2 of Schedule 7 the licence holder may act as a qualified person.

(4) A qualified person may be treated by the licence holder as satisfying the requirements of Part 1 or 2 of Schedule 7 if that person produces evidence that he or she—

(a) is a member of a body specified in paragraph (5); and

(b) is regarded by that body as satisfying those requirements.

(5) Those bodies are—

(a) the Society of Biology;

(b) the Royal Pharmaceutical Society;

(c) the Pharmaceutical Society of Northern Ireland;

(d) the Royal Society of Chemistry; and

(e) such other body as may be specified by the licensing authority for the purpose of this paragraph.

(6) Where the qualified person changes, the licence holder must give the licensing authority advance notification of—

(a) that change; and

(b) the name, address and qualifications of the new qualified person.

(7) The licence holder must not permit any person to act as a qualified person other than the person named in the licence or another person notified to the licensing authority under paragraph (6).

(8) Paragraph (9) applies if the licensing authority thinks, after giving the licence holder and a person acting as a qualified person the opportunity to make representations (orally or in writing), that the person—

(a) does not satisfy the requirements of Part 1 or 2 of Schedule 7 in relation to qualifications or experience;

(b) does not satisfy paragraph (b) of the definition of "qualified person" in regulation 8; or

(c) is failing to carry out the duties referred to in paragraph (2) adequately or at all.

(9) Where this paragraph applies, the licensing authority must notify the licence holder in writing that the person is not permitted to act as a qualified person.

(10) The licence holder must at all times provide and maintain such staff, premises and equipment as are necessary to enable the qualified person to carry out the duties referred to in paragraph (2).

(11) The licence holder is not obliged to meet the requirements of this regulation in relation to any activity under the licence which relates to special medicinal products or to products authorised on a temporary basis under regulation 174 (supply in response to spread of pathogenic agents etc).

Conditions for holding a wholesale dealer's licence

Conditions for wholesale dealer's licence

42.—(1) Regulations 43 to 45 apply to the holder of a wholesale dealer's licence (referred to in those regulations as "the licence holder") and have effect as if they were provisions of the licence (but the provisions specified in paragraph (2) do not apply to the holder of a wholesale dealer's licence insofar as the licence relates to exempt advanced therapy medicinal products).

(2) Those provisions are regulations 43(2), (5) and (8) and 44.

(3) The requirements in Part 2 of Schedule 6 apply to the holder of a wholesale dealer's licence insofar as the licence relates to exempt advanced therapy medicinal products, and have effect as if they were provisions of the licence.

Obligations of licence holder

43.—(1) The licence holder must comply with the guidelines on good distribution practice published by the European Commission in accordance with Article 84 of the 2001 Directive.

(2) The licence holder must ensure, within the limits of the holder's responsibility, the continued supply of medicinal products to pharmacies, and other persons who may lawfully sell medicinal products by retail or supply them in circumstances corresponding to retail sale, so that the needs of patients in the United Kingdom are met.

(3) The licence holder must provide and maintain such staff, premises, equipment and facilities for the handling, storage and distribution of medicinal products under the licence as are necessary—

(a) to maintain the quality of the products; and

(b) to ensure their proper distribution.

(4) The licence holder must inform the licensing authority of any proposed structural alteration to, or discontinuance of use of, premises to which the licence relates or which have otherwise been approved by the licensing authority.

(5) Subject to paragraph (6), the licence holder must not sell or supply a medicinal product, or offer it for sale or supply, unless—

(a) there is a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration (an "authorisation") in force in relation to the product; and

(b) the sale or supply, or offer for sale or supply, is in accordance with the authorisation.

(6) The restriction in paragraph (5) does not apply to—

(a) the sale or supply, or offer for sale or supply, of a special medicinal product;

(b) the export to an EEA State, or supply for the purposes of such export, of a medicinal product which may be placed on the market in that State without a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration by virtue of legislation adopted by that State under Article 5(1) of the 2001 Directive; or

(c) the sale or supply, or offer for sale or supply, of an unauthorised medicinal product where the Secretary of State has temporarily authorised the distribution of the product under regulation 174.

(7) The licence holder must—

(a) 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 paragraph (b);

(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, Article 126a authorisation, certificate of registration or traditional herbal registration for, the product; and

(c) keep records, in relation to the receipt and dispatch of medicinal products, of—

(i) the date of receipt,

(ii) the date of despatch,

(iii) the name of the medicinal product,

(iv) the quantity of the product received or dispatched, and

(v) the name and address of the person from whom the products were received or to whom they are dispatched.

(8) The licence holder must notify the licensing authority and the holder of a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration (an "authorisation") in relation to a medicinal product if the licence holder intends to import the product from another EEA State and is neither—

(a) the holder of an authorisation in relation to the product; nor

(b) acting on behalf of the holder of an authorisation.

(9) For the purposes of enabling the licensing authority to determine whether there are grounds for suspending, revoking or varying the licence, the licence holder must permit a person authorised in writing by the licensing authority, on production of identification, to carry out any inspection, or to take any samples or copies, which an inspector could carry out or take under Part 16 (enforcement).

(10) 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.

Requirement for wholesale dealers to deal only with specified persons

44.—(1) The licence holder may 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; or

(b) a person who holds an authorisation granted by another EEA State authorising the manufacture of products of that description or their distribution by way of wholesale dealing.

(2) 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.

(3) Where a medicinal product is supplied to a person pursuant to paragraph (2)(c), the licence holder must enclose with the product a document stating—

(a) the date on which the supply took place;

(b) the name and pharmaceutical form of the product supplied;

(c) the quantity of product supplied; and

(d) the name and address of the licence holder.

(4) The licence holder must—

(a) keep a record of information supplied in accordance with paragraph (3) 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.

Requirement as to responsible persons

45.—(1) The licence holder must ensure that there is available at all times at least one person (referred to in this regulation as the "responsible person") who in the opinion of the licensing authority—

(a) has knowledge of the activities to be carried out and of the procedures to be performed under the licence which is adequate to carry out the functions mentioned in paragraph (2); and

(b) has adequate experience relating to those activities and procedures.

(2) Those functions are—

(a) ensuring that the conditions under which the licence was granted have been, and are being, complied with; and

(b) ensuring that the quality of medicinal products handled by the licence holder is being maintained in accordance with the requirements of the marketing authorisations, Article

126a authorisations, certificates of registration or traditional herbal registrations applicable to those products.

(3) The licence holder must notify the licensing authority of—

(a) any change to the responsible person; and

(b) the name, address, qualifications and experience of the responsible person.

(4) The licence holder must not permit any person to act as a responsible person other than the person named in the licence or another person notified to the licensing authority under paragraph (3).

(5) Paragraph (6) applies if, after giving the licence holder and a person acting as a responsible person the opportunity to make representations (orally or in writing), the licensing authority thinks that the person—

(a) does not satisfy the requirements of paragraph (1) in relation to qualifications or experience; or

(b) is failing to carry out the functions referred to in paragraph (2) adequately or at all.

(6) Where this paragraph applies, the licensing authority must notify the licence holder in writing that the person is not permitted to act as a responsible person.