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.