STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 16

Enforcement

Validity of decisions and proceedings

322.—(1) The validity of a decision of the licensing authority under Parts 3 (manufacturing and wholesale dealing), 5 (UK marketing authorisations), 6 (certification of homoeopathic medicinal products), 7 (traditional herbal medicinal products) or 8 (Article 126a authorisations) is not to be questioned in any legal proceedings.

(2) The validity of a licence, authorisation, certificate or registration granted or issued, or other thing done, in pursuance of a decision of a kind mentioned in paragraph (1) is not to be questioned in any legal proceedings.

(3) Paragraphs (1) and (2) are subject to the following provisions of this regulation.

(4) A person to whom notice of the decision is given may make an application to the High Court to challenge the validity of the decision on the grounds that—

(a) the decision is not within the powers conferred on the licensing authority; or

(b) a requirement of these Regulations in connection with the matter to which the decision relates has not been complied with.

(5) An application under paragraph (4) must be made within the period of three months beginning immediately after the day on which notice of the decision is given to the applicant.

(6) On an application under paragraph (4) the High Court may—

(a) make an interim order suspending the operation of the decision to which the application relates until the final determination of proceedings; or

(b) quash the decision, if satisfied that—

(i) the decision is not within the powers conferred by these Regulations, or

(ii) the interests of the applicant have been substantially prejudiced by a failure to comply with a requirement under these Regulations.

(7) If a decision to grant a licence, authorisation, certificate or registration is quashed under this regulation—

(a) a licence, authorisation, certificate or registration granted in pursuance of the decision is void; and

(b) the application process for the grant of the licence, authorisation, certificate or registration may be continued as if the decision had not been made.

(8) In the application of this regulation to Scotland, references to the High Court are to be construed as references to the Court of Session.

Enforcement in England, Wales and Scotland

323.—(1) The Secretary of State must enforce or secure the enforcement of these Regulations and the relevant EU provisions in England, Wales and Scotland.

(2) The Secretary of State may make arrangements for either or both of—

(a) the General Pharmaceutical Council; or

(b) in respect of each area for which there is a drugs authority, the drugs authority for the area,

to enforce the provisions of these Regulations listed in paragraph (3) to the extent specified in the arrangements.

(3) The provisions referred to in paragraph (2) are—

(a) regulations 251 (compliance with standards specified in certain publications) and 255(1)(e) (offences relating to dealings with medicinal products: compliance with standards specified in certain publications);

(b) Part 13 (packaging and leaflets); and

(c) Part 14 Chapter 2 (requirements relating to advertising).

(4) Arrangements made with the General Pharmaceutical Council under paragraph (2)(a) in relation to Part 14 Chapter 2 are to be limited to the enforcement of those provisions in respect of—

(a) advertisements displayed or representations made on or in any premises where medicinal products are sold by retail or supplied in circumstances corresponding to retail sale;

(b) advertisements displayed on any web site associated with such premises; and

(c) advertisements displayed on, or in close proximity to, a vending machine in which medicinal products are offered or exposed for sale.

(5) The General Pharmaceutical Council must continue to enforce—

(a) regulations 214 (sale or supply of prescription only medicines) and 220 (sale or supply of medicines not subject to general sale); and

(b) in their application to or in relation to premises that are registered pharmacies, the provisions of these Regulations to which paragraph (7) applies.

(6) In each area for which there is a drugs authority, that drugs authority must continue to enforce the provisions of these Regulations to which paragraph (7) applies in their application to or in relation to premises that are not registered pharmacies.

(7) This paragraph applies to regulations 221 (sale or supply of medicinal products subject to general sale) and 222 (sale of medicinal products from automatic machines).

(8) Functions conferred by virtue of paragraphs (2), (5) and (6) are to be exercised concurrently with the Secretary of State.

(9) Nothing in this regulation confers a function on a person in relation to—

(a) a hospital (except so much of the hospital as is a registered pharmacy); or

(b) so much of any premises as is used as a doctor's or dentist's practice.

(10) In this regulation "drugs authority" means—

(a) in England—

(i) in relation to a non-metropolitan county, metropolitan district or London borough, the council of that county, district or borough, and

(ii) in relation to the City of London (including the Inner Temple and the Middle Temple), the Common Council of the City of London;

(b) in Wales, the council of a county or county borough; and

(c) in Scotland, a council constituted in relation to a local government area under section 2 of the Local Government etc (Scotland) Act 1994(**1**).

(11) In this Part "premises" includes—

(a) any place; and

(b) a ship, aircraft, hovercraft or vehicle.

(12) Nothing in this regulation is to be construed as authorising any person other than the Lord Advocate or a procurator fiscal to institute proceedings in Scotland for an offence.

Enforcement in Northern Ireland

324.—(1) The Minister for Health, Social Services and Public Safety (in this regulation referred to as "the Minister") must enforce or secure the enforcement of these Regulations and the relevant EU provisions in Northern Ireland.

(2) The Minister may make arrangements for a district council to enforce the provisions of these Regulations listed in paragraph (3) in its district to the extent specified in the arrangements.

(3) Those provisions are—

(a) regulations 221 (sale or supply of medicinal products subject to general sale), 222 (sale of medicinal products from automatic machines) and 255(6) (certain offences relating to dealings with medicinal products);

(b) regulations 251 (compliance with standards specified in certain publications) and 255(1)(e) (certain offences relating to dealings with medicinal products);

(c) Part 13 (packaging and leaflets); and

(d) Part 14 Chapter 2 (requirements relating to advertising).

(4) Functions conferred by virtue of paragraph (2) are to be exercised concurrently with the Minister.

(5) Regulation 323(9) has effect in relation to functions conferred by this regulation as it has effect in relation to functions conferred by regulation 323.

(6) In this regulation, "district council" means a council established under the Local Government Act (Northern Ireland) 1972(**2**).

Rights of entry

325.—(1) An inspector may at any reasonable time enter premises—

(a) in order to determine whether there has been a contravention of a provision of these Regulations which the enforcement authority is required or empowered to enforce by virtue of regulations 323 and 324;

(b) in order to verify whether the data submitted in respect of an active substance used as a starting material in order to obtain a conformity certificate issued by the European Directorate for the Quality of Medicines and Healthcare ("EDQM") comply with the monographs of the European Pharmacopoeia, if the EDQM asks the enforcement authority to do so; and

(c) for the purposes of any other function of the enforcement authority under these Regulations.

(2) A person may not exercise a right of entry under this regulation in relation to premises used only as a private dwelling unless 24 hours' notice has been given to the occupier.

(**1**) 1994 c.39. There is an amendment to section 2(1) that is not relevant to this regulation.
(**2**) 1972 c.9 (N.I.).

(3) A person exercising, or attempting to exercise, a right of entry under this regulation must produce identification on request.

Application for warrant

326.—(1) In a case where this regulation applies, a justice of the peace may issue a warrant authorising an inspector to enter premises, by force if necessary.

(2) This regulation applies if, on sworn information in writing, the justice of the peace is satisfied that—

(a) there are reasonable grounds for entering the premises by virtue of the enforcement authority's functions under these Regulations;

(b) an inspector has a right to enter them by virtue of regulation 325; and

(c) a condition specified in paragraph (3) is satisfied.

(3) Those conditions are—

(a) that—

(i) admission to the premises has been refused or is expected to be refused, and

(ii) notice of the intention to apply for a warrant has been given to the occupier;

(b) that a request for admission, or the giving of notice, would defeat the object of the entry;

(c) that the case is one of urgency; or

(d) that the premises are unoccupied or the occupier is temporarily absent.

(4) In relation to a ship, aircraft, hovercraft or vehicle, references in this Part to the occupier of premises are to be read as references to the master, commander or other person in charge of the ship, aircraft, hovercraft or vehicle.

(5) A warrant granted under this regulation continues in force for a period of 30 days beginning with the day on which the warrant is granted.

(6) In the application of this regulation to England, references to a justice of the peace include a reference to a district judge (magistrates' courts).

(7) In the application of this regulation to Scotland, references to a justice of the peace are to be read as references to a sheriff, stipendiary magistrate or justice of the peace.

(8) In the application of this regulation to Northern Ireland, references to a justice of the peace are to be read as references to a lay magistrate or a district judge (magistrates' courts).

Powers of inspection, sampling and seizure

327.—(1) An inspector may inspect anything mentioned in paragraph (2)—

(a) in order to determine whether there has been a contravention of any provision of these Regulations which the enforcement authority must or may enforce by virtue of regulations 323 and 324;

(b) for the purpose described in regulation 325(1)(b) (verification of data at the request of the European Directorate for the Quality of Medicines and Healthcare); or

(c) in order to verify any statement made by an applicant for a manufacturer's or wholesale dealer's licence, marketing authorisation, certificate of registration, traditional herbal registration or Article 126a authorisation in an application under Parts 3 or 5 to 8.

(2) The things mentioned in paragraph (1) are—

(a) a substance or article appearing to the inspector to be a medicinal product;

(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

(ii) a label or leaflet used or intended to be used in connection with a medicinal product;

(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;

(d) any process of manufacture or assembly of medicinal products;

(e) the way in which medicinal products, or the materials used in the manufacture of medicinal products, are tested at any stage in the process of manufacture or assembly; and

(f) information and documents relating to the manufacture, assembly, importation, sale, supply or advertising of, or wholesale dealing in, medicinal products;

(g) information and documents relating to the safety of medicinal products, 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) or 14(8) of Regulation (EC) No 726/2004, and

(iv) the requirements of Chapter 3 (pharmacovigilance) of Title II of Regulation (EC) No 726/2004.

(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 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.

(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 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.

(5) The inspector may take copies of information or documents—

(a) inspected under sub-paragraph (2)(f) or (g); or

(b) produced under paragraph (4).

(6) The inspector may seize and retain a substance or article appearing to the inspector to be a medicinal product 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.

(7) The inspector may, if the inspector reasonably believes that it may be required as evidence in proceedings, seize and retain—

(a) any document; or

(b) anything inspected, or discovered in the course of an inspection, under paragraph (1).

(8) The inspector may, if necessary, require a person who has the authority to do so—

(a) to open a container or package;

(b) to open a vending machine; or

(c) to allow the inspector to open a container, package or vending machine,

for the purpose of enabling the inspector to seize a substance, article, document or other thing under paragraph (6) or (7).

(9) The information and documents referred to in this regulation include any that are stored electronically.

Regulation 327: supplementary

328.—(1) Where an inspector seizes a substance, article, document or other thing under regulation 327(6) or (7) (powers of inspection, sampling and seizure) the inspector—

(a) must, where practicable, inform—

(i) the person, if any, from whom it was seized, and

(ii) the occupier of the premises from which it was seized; or

(b) in relation to anything seized from a vending machine, must inform—

(i) the person whose name and address are stated on the machine to be those of the machine's owner, or

(ii) if no name and address are stated, the occupier of the premises on which the machine stands or to which it is affixed.

(2) An inspector exercising, or attempting to exercise, a right under regulation 327 must produce identification on request.

(3) The provisions of Schedule 31 have effect in relation to samples obtained by inspectors on behalf of enforcement authorities.

Application of sampling procedure to substance or article seized under this Part

329.—(1) This regulation applies where an inspector seizes a substance or article under regulation 327 (powers of inspection, sampling and seizure).

(2) On request in accordance with paragraph (3), the inspector must either—

(a) set aside a sample of the substance or article seized; or

(b) treat the substance or article as a sample,

whichever seems more appropriate having regard to the nature of the substance or article.

(3) A request is made in accordance with this paragraph if—

(a) it is made by a person ("P") who is entitled to be informed of the seizure under regulation 328; and

(b) it is made either at the time of the seizure or within the period of 21 days beginning with the day immediately after the day on which P is informed of the seizure.

(4) An inspector is not required by paragraph (2) to set aside a sample, or to treat a substance or article as a sample, if the nature of the substance or article is such that it is not reasonably practicable to do either of those things.

(5) An inspector must—

(a) divide a sample under paragraph (2) into three parts;

(b) mark each part;

(c) seal or fasten each part; and

(d) supply one part to P.

(6) Paragraphs 10 to 12 and 15 to 26 of Schedule 31 apply to a sample under this regulation as they apply to a sample obtained as mentioned in paragraph 1 of that Schedule, but as if—

(a) references to the preceding provisions of that Schedule were references to the preceding provisions of this regulation;

(b) references to a sampling officer were references to an inspector who seized a substance or article under regulation 327 (powers of inspection, sampling and seizure); and

(c) a reference to the relevant enforcement authority were a reference to the authority by which the inspector is authorised.

Analysis of samples: other cases

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

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

(3) Paragraphs 2 to 13 of Schedule 31 have effect, in relation to a person proposing to submit a sample in pursuance of paragraph (2), as if in that Schedule references to the sampling officer were references to that person.

(4) A public analyst to whom a sample is submitted under this regulation must analyse the sample, or cause it to be analysed, as soon as practicable (but this is subject to the following provisions of this regulation).

(5) If the public analyst to whom a sample is submitted thinks that a proper analysis cannot be carried out for any reason, the public analyst must send it to the public analyst for some other area, who must as soon as practicable analyse the sample, or cause it to be analysed (subject to paragraph 6).

(6) A public analyst to whom a sample is submitted or sent under this regulation may demand payment in advance of the required fee, and if payment in advance is demanded may refuse to carry out the analysis until the fee is paid.

(7) A public analyst who has analysed a sample or caused it to be analysed must issue a certificate specifying the result of the analysis to the person by whom the sample was submitted under paragraph (2).

(8) Paragraphs 21 to 23 of Schedule 31 have effect in relation to a certificate issued under this regulation as they have effect in relation to a certificate issued under paragraph 19 of that Schedule.

(9) In this regulation "public analyst"—

(a) in relation to England and Wales and Scotland has the meaning given by section 27 of the Food Safety Act 1990(**3**); and

(b) in relation to Northern Ireland has the meaning given by Article 27(1) of the Food Safety (Northern Ireland) Order 1991(**4**).

Findings and reports of inspections

331.—(1) If the outcome of the inspection of things referred to in regulation 327(2)(g) (powers of inspection, sampling and seizure: information and documents relating to safety etc) is that

(**3**) 1990 c.16. Section 27 was amended by the Local Government etc (Scotland) Act 1994 section 180(1) and Schedule 18 paragraph 163(3), the Food Standards Act 1999 section 40(1) and Schedule 5 paragraphs 7 and 8, the Local Government (Wales) Act 1994 section 22(3) and Schedule 9 paragraph 16(2), S.I. 1994/865 regulation 24, and the Local Government and Public Involvement in Health Act 2007 sections 22 and 241, Schedule 1 Part 2 paragraph 17, and Schedule 18 Part 1.

(**4**) 1991 No. 762 (N.I. 7). There are amendments not relevant to these Regulations.

the holder of a marketing authorisation or traditional herbal registration does not comply with the pharmacovigilance system as described in the pharmacovigilance system master file, or any provision of Part 11 (pharmacovigilance), the enforcement authority must—

(a) bring the deficiencies to the attention of the holder;

(b) give the holder the opportunity to submit comments; and

(c) inform the other EEA States, the EMA and the European Commission.

(2) Paragraph (1) is without prejudice to paragraphs (3) and (5).

(3) After every inspection carried out in accordance with regulations 325 (rights of entry) and 327 (powers of inspection, sampling and seizure) in connection with medicinal products other than registrable homoeopathic medicinal products, the enforcement authority must report on whether the activities to which the inspection relates comply with such of the provisions mentioned in paragraph (4) as apply to those activities.

(4) Those provisions are—

(a) the Good Manufacturing Practice Directive and any principles or guidelines of good manufacturing practice referred to in Article 47 of the 2001 Directive;

(b) the guidelines on good distribution practice referred to in Article 84 of the 2001 Directive; and

(c) in the case of the holder of a marketing authorisation or traditional herbal registration—

(i) Part 11 (pharmacovigilance), and

(ii) Chapter 3 (pharmacovigilance) of Title II (authorisation and supervision of medicinal products for human use) of Regulation (EC) No 726/2004.

(5) The enforcement authority must before adopting the report —

(a) communicate the content of the report to the person to whose activities the inspection relates; and

(b) give that person the opportunity to submit comments.

Restrictions on disclosure of information

332.—(1) A person ("P") must not disclose to another person, otherwise than in the performance of P's functions—

(a) any information relating to a manufacturing process or trade secret obtained by P on premises which P has entered by virtue of regulation 325 or of a warrant under regulation 326; or

(b) any information obtained by P or given to P in pursuance of these Regulations.

(2) Paragraph (1) does not apply if—

(a) P is, or is acting on behalf of, a public authority for the purposes of the Freedom of Information Act 2000(**5**); and

(b) the information is not held by the authority on behalf of another person.

Protection for inspectors

333.—(1) An inspector is not personally liable in respect of any act done in the execution, or purported execution, of a function under these Regulations and within the scope of the inspector's employment by an enforcement authority (or, where the inspector is not employed by the authority,

(**5**) 2000 c.36.

the scope of the inspector's authorisation), provided that the act was done in the honest belief that these Regulations required or permitted it.

(2) Where an action is brought against an inspector in respect of an act falling within paragraph (1), the enforcement authority may indemnify the inspector against any damages, costs or expenses incurred, if the authority is satisfied that the inspector honestly believed that these Regulations required or permitted the act.

(3) Paragraph (2) applies in a case where the person is not legally entitled to require an indemnity from the enforcement authority.

(4) A reference to an inspector in this regulation includes a reference to an employee of the licensing authority who accompanies an inspector pursuant to regulation 334(1).

Supplementary provisions and offences

334.—(1) An inspector entering any premises by virtue of regulation 325 or of a warrant under regulation 326 may be accompanied by such persons, and take such equipment, as the inspector thinks appropriate.

(2) Where an inspector enters premises in pursuance of a warrant under regulation 326, the inspector must, if the property is unoccupied or the occupier is temporarily absent, leave the premises as effectively secured against trespass as they were before the inspector entered.

(3) It is an offence for a person—

(a) intentionally to obstruct an inspector;

(b) intentionally to fail to comply with a requirement properly made under regulation 327 by an inspector; or

(c) without reasonable cause, to fail to give an inspector any other assistance or information which the inspector may reasonably require in order to perform a function under these Regulations.

(4) A person guilty of an offence under paragraph (3) is liable on summary conviction to a fine not exceeding level 3 on the standard scale.

(5) A person who knowingly makes a false statement in giving information as mentioned in paragraph (3)(c) is guilty of an offence.

(6) A person who breaches the prohibition in regulation 332(1) (restrictions on disclosure of information) is guilty of an offence.

(7) A person who is guilty of an offence under paragraph (5) or (6) is liable—

(a) on summary conviction to a fine not exceeding the statutory maximum; or

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

(8) Nothing in this regulation is to be read as requiring a person to answer a question or to give information if doing so might incriminate that person or the spouse or civil partner of that person.

(9) In this regulation "occupier", in relation to a ship, aircraft, or vehicle, is to be read in accordance with regulation 326(4).