STATUTORY INSTRUMENTS.

S.I. No. 538 of 2007

MEDICINAL PRODUCTS (CONTROL OF WHOLESALE DISTRIBUTION) REGULATIONS 2007

(Prn. A7/1459)

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ARRANGEMENT OF REGULATIONS

SCHEDULES

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MEDICINAL PRODUCTS (CONTROL OF WHOLESALE DISTRIBUTION) REGULATIONS 2007

The Minister for Health and Children, in exercise of the powers conferred on her by section 32 of the Irish Medicines Board Act 1995 (No. 29 of 1995), as amended by section 16 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006 (No. 3 of 2006) and as adapted by the Health (Alteration of Name of Department and Title of Minister) Order 1997 (S.I. No. 308 of 1997) and including for the purpose of giving effect to Title VII of Directive 2001/83/EC (as amended by Directive 2004/27/EC), hereby make the following regulations:—

Citation

1. These Regulations may be cited as the Medicinal Products (Control of Wholesale Distribution) Regulations 2007.

Commencement

2. These Regulations shall come into force on 23 July 2007.

Revocation

3. The Medical Preparations (Wholesale Licences) Regulations 1993 (S.I. No. 39 of 1993) (as amended) are hereby revoked.

Interpretation

4. (1) In these Regulations:

'Act' means the Irish Medicines Board Act 1995 as amended by the Irish Medicines Board (Miscellaneous Provisions) Act 2006 and by the European Communities (Amendment of the Irish Medicines Board Act 1995) Regulations 2007 (S.I. No. 542 of 2007);

'authorisation holder' means the holder of a wholesaler's authorisation;

'Board' means the Irish Medicines Board established by section 3 of the Irish Medicines Board Act 1995;

'certificate of registration' means a certificate of registration which is for the time being in force and which has been granted by the Board under the Medicinal Product (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007) in respect of a homeopathic medicinal product that satisfies the conditions specified in Article 14(1) of the 2001 Directive;

'certificate of traditional-use registration' means a certificate of traditional-use registration which is for the time being in force and which has been granted by the Board under the Medicinal Products (Control of Placing on the Market) Regulations 2007 in respect of a traditional herbal medicinal product;

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 31*st July*, 2007.

'Commission' means the Commission of the European Community;

'2001 Directive' means Directive 2001/83/EC[1] of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use, as amended by Directives 2002/98/EC[2], 2004/24/EC[3] and 2004/27/EC[4] of the European Parliament and of the Council;

'dispensing pharmacy' means a shop being lawfully kept open for the dispensing or compounding of medical prescriptions under the Pharmacy Acts 1875 to 1977 and includes the pharmaceutical department of a hospital;

'EEA Agreement' means the Agreement on the European Economic Area signed in Oporto on 2 May 1992 as adjusted by the Protocol to that Agreement done at Brussels on 17 March 1993[5];

'EEA State' means a State which is a contracting party to the EEA Agreement;

'European Economic Area' means the European Economic Area created by the EEA Agreement;

'exempt sourced medicinal product' means an exempt medicinal product that is either imported from another EEA State or is sourced in the State from the holder of a manufacturer's authorisation;

'exempt medicinal product' means a medicinal product to which paragraph 2 of Schedule 1 to the Medicinal Products (Control of Placing on the Market) Regulations 2007, or any equivalent legislation in any EEA State other than the State, applies;

'herbal medicinal product' means any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations;

'herbal preparations' mean preparations obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation. These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates;

'herbal substances' mean all mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried, form, but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author);

[1]OJ L. 311, 28.11.2001, p.67.
[2]OJ L. 33, 08.02.2002, p.30.
[3]OJ L. 136, 30.04.2004, p.85.
[4]OJ L. 136, 30.4.2004, p.34.
[5]OJ No. L 1, 03.01.1994, p.572.

'homeopathic medicinal product' means any medicinal product, which may contain a number of principles, prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in an EEA State. The term also includes anthroposophic medicinal products described in an official pharmacopoeia and prepared by a homeopathic method;

'manufacturer's authorisation' means an authorisation granted and in force in pursuance of Regulation 8 of the Medicinal Products (Control of Manufacture) Regulations 2007 (S.I. No. 539 of 2007);

'marketing authorisation' means an authorisation which is for the time being in force and which has been granted by the Board under the Medicinal Products (Control of Placing on the Market) Regulations 2007 or by the Commission under Regulation (EEC) No. 2309/93[6] or Regulation (EC) No 726/2004[7] and includes a marketing authorisation issued by the competent authority of an EEA State, other than the State, in accordance with the 2001 Directive;

'Minister' means the Minister for Health and Children;

'pharmacist' means a registered pharmaceutical chemist, or a registered dispensing chemist and druggist, under the Pharmacy Acts 1875 to 1977;

'pre-hospital emergency care provider' has the same meaning as in the Pre-Hospital Emergency Care Council (Establishment) Order 2000, as amended by the Pre-Hospital Emergency Care Council (Establishment) Order 2000 (Amendment) Order 2004 (S.I. No. 575 of 2004);'

'registered dentist' means a person registered in the register established under the Dentists Act 1985 (No. 9 of 1985);

'registered dispensing optician' means a person registered in the register of dispensing opticians established under the Opticians Acts 1956 and 2003;

'registered medical practitioner' means a person registered in the register established under the Medical Practitioners Act 1978 (No. 4 of 1978);

'registered optometrist' means a person registered in the Register of Optometrists established under the Opticians Acts 1956 to 2003;

'registered veterinary practitioner' means a person registered in the register established under the Veterinary Practice Act 2005 (No. 22 of 2005);

'responsible person' means the person referred to in paragraph 6 of Schedule 2;

'sale by wholesale' means sale or supply for the purposes of sale in the course of a business or for administration to patients in the course of a professional practice and cognate words shall be construed accordingly. Such term shall also

[6]OJ No. L.214, 24.08.1993, p.1
[7] OJ No. L 136, 30.04.2004, p. 1.

include all activities consisting of the procuring, holding or exporting of medicinal products other than activities involving the sale or supply of such products to the public;

'traditional herbal medicinal product' means a herbal medicinal product that satisfies the conditions specified in Article 16a of the 2001 Directive;

'wholesaler's authorisation' means an authorisation which is for the time being in force and which has been granted by the Board in pursuance of Regulation 9.

(2) In these Regulations, unless the context otherwise requires—

(*a*) any reference to a Regulation or Schedule shall be construed as a reference to a Regulation contained in these Regulations or, as the case may be, to a Schedule thereto, and

(*b*) any reference in a Regulation, or a Schedule, to a paragraph shall be construed as a reference to a paragraph in that Regulation or Schedule and in a paragraph, any reference to a subparagraph shall be construed as a reference to a subparagraph in that paragraph.

(3) A word or expression which is used in these Regulations and which is also used in the 2001 Directive has, unless the context otherwise requires, the same meaning in these Regulations as it has in that Directive.

Requirement for authorisation to sell medicinal products by wholesale

5. Subject to the provisions of these Regulations, a person shall not sell by wholesale, or offer or keep for sale by wholesale, any medicinal product unless he or she is the holder of a wholesaler's authorisation.

Exemptions

6. The provisions of Regulation 5 shall not apply to—

(*a*) the sale by wholesale of a medicinal product by a person who has manufactured or imported it under and in accordance with the provisions of a manufacturer's authorisation;

(*b*) the supply of an investigational medicinal product in accordance with Regulation 11 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (S.I. No. 190 of 2004).

(*c*) (i) the sale by or under the personal supervision of a pharmacist in a dispensing pharmacy, to a person to which this subparagraph applies, for administration to patients in the course of a professional practice or service.

(ii) the persons to which subparagraph (i) applies are a registered medical practitioner, a registered dentist, a registered dispensing optician, a registered optometrist, a registered veterinary surgeon, a person who is acting as a pre-hospital emergency care provider

and a person lawfully entitled to obtain medicinal products for administration to patients in the course of a business as a hospital.

Application for a wholesaler's authorisation

7. (1) An application for the grant of a wholesaler's authorisation shall—

(*a*) be made in writing to the Board; and

(*b*) be signed by or on behalf of the applicant, whether in ink or by means of an electronic signature.

(2) Every application for the grant of a wholesaler's authorisation shall be accompanied by—

(*a*) the particulars specified in Schedule 1 to these Regulations;

(*b*) a written undertaking that, in the event of the authorisation being granted, he or she will ensure fulfillment of the obligations arising by virtue of the terms and conditions of the authorisation; and

(*c*) any fee which may be payable in connection with that application.

Consideration of application for a wholesaler's authorisation

8. (1) Subject to the provisions of this regulation, the Board shall consider a valid application for a wholesaler's authorisation and grant or refuse to grant an authorisation within a period not exceeding 90 days from the date the application is received.

(2) Following receipt of an application, the Board shall, by means of inspection or otherwise, confirm the accuracy of the particulars provided in the application as referred to in Regulation 7(2) and may give a notice in writing to the applicant requesting him or her to provide further information relating to those particulars.

(3) Where the Board gives a notice pursuant to paragraph (2), the period specified in paragraph (1) shall be suspended from the date the notice is given and shall recommence only on receipt of the information requested.

(4) The expiry of the period of 90 days referred to in paragraph (1) shall not be taken to mean that an implicit wholesaler's authorisation has been granted.

(5) In this Regulation, 'valid application' means an application, which complies with the provisions of Regulation 7.

Grant or refusal of wholesaler's authorisation

9. (1) The Board shall grant a wholesaler's authorisation only if—

(*a*) the applicant—

(i) has complied with the requirements of Regulation 7,

(ii) has at his or her disposal suitable and sufficient premises, installations and equipment, so as to ensure proper conservation and distribution of the medicinal products,

(iii) has appropriate and sufficient staff, including a responsible person, to enable the holder of such authorisation to effectively comply with any provisions contained in the authorisation pursuant to paragraph (3),

(iv) if a notice has been given under Regulation 8(2), has provided the information requested by the Board; and

(*b*) it has established that the particulars supplied pursuant to Regulation 7(2) are accurate.

(2) Subject to paragraph (1), the Board may grant a wholesaler's authorisation in respect of any or all of—

(*a*) the descriptions of medicinal products; and

(*b*) the premises,

specified in the application made pursuant to Regulation 7.

(3) Subject to paragraph (1), the Board may—

(*a*) grant a wholesaler's authorisation in accordance with the application,

(*b*) grant a wholesaler's authorisation in accordance with the application, but subject to the carrying out of certain obligations by the authorisation holder as may be specified in the authorisation,

(*c*) grant a wholesaler's authorisation otherwise than in accordance with the application, or

(*d*) refuse to grant a wholesaler's authorisation.

(4) The provisions of Schedule 3 shall have effect where the Board proposes—

(*a*) to grant a wholesaler's authorisation in accordance with the application, but subject to the carrying out of certain obligations by the authorisation holder,

(*b*) to grant a wholesaler's authorisation otherwise than in accordance with the application, or

(*c*) to refuse to grant a wholesaler's authorisation.

(5) Where the Board—

(*a*) grants a wholesaler's authorisation in accordance with the application, but subject to the carrying out of certain obligations by the authorisation holder,

(*b*) grants a wholesaler's authorisation otherwise than in accordance with the application, or

(*c*) refuses to grant a wholesaler's authorisation,

the Board shall give the applicant a notice in writing stating in detail the reasons on which its decision is based.

Application and effect of wholesaler's authorisation

10. A wholesaler's authorisation shall apply only in relation to—

(*a*) the descriptions of medicinal products,

(*b*) the wholesaling operations, and

(*c*) the premises,

specified in the application made pursuant to Regulation 7 and in respect of which the authorisation has been granted.

Obligations of wholesalers of medicinal products

11. Subject to the provisions of these Regulations, an authorisation holder shall not sell by wholesale any medicinal product except in accordance with the requirements set down in Schedule 2 and any further conditions or obligations as may be imposed in the authorisation.

Variation of wholesaler's authorisation

12. (1) The Board may vary a wholesaler's authorisation, whether on the application of the authorisation holder or otherwise.

(2) Subject to the following provisions of this Regulation, if the authorisation holder makes a valid application to vary the wholesaler's authorisation, the Board shall consider the application, and—

(*a*) in a case where the effect of the variation would be to change the—

(i) descriptions of medicinal products,

(ii) the wholesaling operations,

(iii) the premises,

(iv) the installations and equipment,

in respect of which the authorisation has been granted, may vary or refuse to vary the authorisation within a period not exceeding 30 days from the date the application is received;

(*b*) in any other case, may vary or refuse to vary the authorisation within such period as the Board considers appropriate, being a period not exceeding 60 days.

(3) If the application falls within paragraph (2), but it appears to the Board to be necessary to conduct an inspection of any premises to which the variation relates, the Board may vary or refuse to vary the authorisation within a period not exceeding 90 days from the date the application is received.

(4) Following receipt of a valid application to vary a wholesaler's authorisation, the Board may give a notice in writing to the applicant requesting him or her to provide further information relating to the contents of the application or any particulars relevant to the application.

(5) Where the Board gives a notice pursuant to paragraph (4), and a period specified in paragraph (2) or paragraph (3) applies, that period shall be suspended from the date the notice is given and shall recommence only on receipt of the information requested.

(6) The provisions of Schedule 3 shall have effect where the Board—

(*a*) proposes to vary a wholesaler's authorisation, otherwise than in accordance with a valid application by the authorisation holder; or

(*b*) proposes to refuse to vary a wholesaler's authorisation, after consideration of the application of the holder.

(7) Where the Board—

(*a*) varies a wholesaler's authorisation, otherwise than in accordance with a valid application by the authorisation holder; or

(*b*) after consideration of such an application, refuses to vary a wholesaler's authorisation,

the Board shall notify the holder of that authorisation in writing, stating in detail the reasons on which its decision is based.

(8) In this Regulation, 'valid application' means an application—

(*a*) made to the Board in writing and signed by or on behalf of the applicant, whether in ink or by means of an electronic signature;

(*b*) specifying the variation requested by the applicant; and

(*c*) accompanied by—

(i) such particulars as are necessary to enable the Board to consider the application, and

(ii) any fee which may be payable in connection with that application.

Suspension and revocation of wholesaler's authorisation

13. (1) The Board may by a notice in writing to the authorisation holder, forthwith or from a date specified in the notice, suspend the authorisation for such period as the Board may determine, or revoke the authorisation, on one or more of the following grounds—

(*a*) the holder is not carrying out, or has indicated by a notice in writing that he or she no longer intends to carry out, the wholesaling operations to which the authorisation relates;

(*b*) the particulars accompanying the application in accordance with Regulation 7(2), were false or incomplete in a material particular;

(*c*) a material change of circumstances has occurred in relation to any of those particulars;

(*d*) the holder has failed to any material extent to comply with his or her obligations under Regulation 11;

(*e*) the holder has sold by wholesale medicinal products otherwise than in accordance with the terms of the authorisation; and

(*f*) the holder does not have the staff, premises, installations or equipment necessary for carrying out properly the handling, storage or distribution activities to which the authorisation relates.

(2) The suspension or revocation of a wholesaler's authorisation under this Regulation may be—

(*a*) total; or

(*b*) limited to medicinal products—

(i) of one or more descriptions, or

(ii) handled, stored or distributed at or from any particular premises or particular part of any premises.

(3) The provisions of Schedule 3 shall have effect where the Board proposes to suspend or revoke a wholesaler's authorisation in accordance with this Regulation.

(4) Where the Board suspends or revokes a wholesaler's authorisation in accordance with this Regulation, it shall notify the holder of that authorisation in writing, stating in detail the reasons on which its decision to suspend or revoke the authorisation is based.

Particular Enforcement Obligations

14. Whether acting through authorised officers appointed under section 32B of the Act or in any other way, and without prejudice to the generality of the provisions of the Act, the Board shall in particular investigate the following:

(*a*) that all wholesalers of medicinal products have obtained an authorisation pursuant to an application under Regulation 7,

(*b*) that wholesalers of medicinal products are complying with the terms and conditions of any such authorisation, and

(*c*) that the wholesaler is complying with his or her obligations pursuant to Regulation 11.

Transitional provisions

15. (1) Subject to paragraph (2), any wholesaler's licence granted under Regulation 7(1) of the Medical Preparations (Wholesale Licences) Regulations 1993 (as amended) and in force on the coming into force of these Regulations, shall continue in force until the date of expiry of such licence, as if granted as a wholesaler's authorisation under these Regulations.

(2) The holders of the licences referred to in paragraph (1) shall make application for a wholesaler's authorisation under Regulation 7, not later than three months before the date on which the said wholesaler's licence is due to expire and where such application has been made, the said licence shall continue in force pending the decision of the Board on that application.

(3) An application made in respect of the grant or renewal of a wholesaler's licence under the Medical Preparations (Wholesale Licences) Regulations 1993 (as amended), and which has not been determined prior to the date of coming into force of these Regulations, shall be considered as if it were an application made under Regulation 7 of these Regulations. In all such cases, where the information provided in such applications is not sufficient, the Board may require that the applicant shall update his or her application to conform to the provisions of Regulation 7.

SCHEDULE 1

Regulation 7(3)

PARTICULARS THAT MUST ACCOMPANY AN APPLICATION FOR A WHOLESALER'S AUTHORISATION

1. The name and address of the applicant, and, where the applicant is not the proposed holder of the wholesaler's authorisation, the name and address of the proposed holder.

2. A statement of the operations to which the wholesaler's authorisation is to relate.

3. A description of the medicinal products in respect of which the authorisation is required.

4. (1) The address of each of the premises where the proposed holder of the wholesaler's authorisation proposes to store medicinal products or from which he or she proposes to distribute them.

(2) A statement indicating the facilities and equipment available, at each of the premises referred to in subparagraph (1), for storing the medicinal products on, and distributing them from or between, such premises.

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

(4) A statement in the form of an emergency plan, setting out the procedures to be implemented in the event of both urgent and non-urgent recalls of medicinal products from the market.

5. (1) The name and address and degrees, diplomas or qualifications and experience of the person who will carry out the functions of the responsible person.

(2) The name, address, qualifications and experience of any other person whose duty it will be to supervise the operations at each of the premises referred to in paragraph 4, and in each case, the name and function of the person to whom he or she is responsible.

6. An outline of the arrangements at each of the premises where the holder of the wholesaler's authorisation stores or proposes to store medicinal products for ensuring, so far as practicable, whether by maintaining records or other means, a satisfactory rotation of stocks of medicinal products.

(Regulation 11)

SCHEDULE 2

REQUIREMENTS TO BE MET BY THE AUTHORISATION HOLDER

1. In this Schedule, the term 'marketing authorisation' includes a certificate of registration and a certificate of traditional-use registration.

2. The authorisation holder shall obtain his or her supplies of medicinal products only from persons—

(*a*) who are themselves the holders of a manufacturer's authorisation or wholesaler's authorisation in respect of such products, or

(*b*) who are the holders of an authorisation granted by the competent authority of another EEA State authorising the manufacture of such products or their wholesale distribution.

3. (1) Subject to subparagraph (2) and paragraph 17, the authorisation holder shall not sell by wholesale any medicinal product—

(*a*) other than a product to which the authorisation relates,

(*b*) unless there has been granted in respect of such product, a marketing authorisation which is for the time being in force, and

(*c*) unless the sale of such product is in conformity with the provisions of its marketing authorisation.

(2) Subparagraph (1)(*b*) and (*c*) shall not apply—

(*a*) until 30 April 2011, to the sale by wholesale of any traditional herbal medicinal product that was already on the market in the State, on the date of the coming into force of these Regulations;

(*b*) to the sale by wholesale of an exempt medicinal product; and

(*c*) to 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 by virtue of legislation adopted by that State under Article 5.2 of the 2001 Directive.

4. The authorisation holder shall only sell medicinal products by wholesale to persons—

(*a*) who are themselves the holders of a wholesaler's authorisation relating to those products,

(*b*) who are the holders of an authorisation granted by the competent authority of another EEA State authorising the wholesale distribution of those products,

(*c*) who are the holders of a manufacturer's authorisation for use in the manufacture of medicinal products to which the said manufacturer's authorisation relates,

(*d*) who are authorised or entitled to supply the said medicinal products to the public, or

(*e*) who are lawfully entitled to administer those products to patients in the course of a professional practice or business as a hospital.

5. The authorisation holder shall provide and maintain such staff, premises, installations, equipment and procedures for the handling, storage and distribution of the medicinal products that he or she handles, stores or distributes under his or her authorisation, as are necessary to avoid deterioration of the products and he or she shall not use for such purposes premises other than those specified in his or her authorisation.

6. (1) The authorisation holder shall at all times have at his or her disposal the services of a responsible person who possesses in the opinion of the Board:

(*a*) knowledge of the activities to be carried out and of the procedures to be performed under the authorisation which is adequate for performing the functions of the responsible person; and

(*b*) experience in those activities and procedures which is adequate for those purposes.

(2) The functions of the responsible person shall be to ensure that in relation to medicinal products—

(*a*) the conditions under which the wholesaler's authorisation has been granted have been, and are being, complied with, and

(*b*) the quality of the products that are being handled by the authorisation holder is maintained in accordance with the requirements of the marketing authorisation that are applicable to those products.

(3) The authorisation holder shall—

(*a*) notify the Board of the name and address and degrees, diplomas or qualifications and experience of the person who will carry out the functions of responsible person;

(*b*) notify the Board of any change to the responsible person; and

(*c*) shall not permit any person to act as responsible person other than the person named in his or her authorisation as the responsible person, or subject to subparagraphs (4) and (5) any other such person whose name is notified to the Board.

(4) Where, after giving the authorisation holder and the person acting as the responsible person the opportunity of making representations (either orally or in writing), the Board is of the opinion that—

(*a*) the person so acting does not satisfy the provisions of subparagraph (1) as respects qualifications and experience, or

(*b*) he or she is failing to carry out the functions referred to in subparagraph (2) adequately or at all,

and has notified the authorisation holder accordingly in writing, the holder shall not permit that person to continue to act as the responsible person so long as the said notification has not been withdrawn by the Board.

(5) The Board may require the authorisation holder to temporarily suspend the person acting as such responsible person upon the commencement of administrative or disciplinary proceedings against him for failure to fulfil his or her functions as referred to in subparagraph (2) and the authorisation holder shall not permit that person to act as the responsible person pending the determination of such proceedings. However, nothing in this paragraph shall affect the right of the responsible person pursuant to his or her contract of employment to receive full pay during the period of any such suspension.

7. The authorisation holder shall notify the Board of any proposed structural alteration to, or discontinuation of use of, premises to which the authorisation relates or premises that have been approved from time to time by the Board.

8. (1) The authorisation holder shall keep available for inspection by officers of the Board, for a period of not less than five years, records giving for each transaction in respect of medicinal products received or dispatched at least the following information:

— the date of receipt or supply,

— the name of the medicinal product,

— the quantity received or supplied, and

— the name and address of the supplier or consignee, as appropriate.

(2) The records referred to in subparagraph (1) may be provided via image medium or other data medium, provided that the data, when made readable, match the original documentation in appearance and content, are available at all times, can be made readable without delay and can be analysed by automated means.

9. The authorisation holder shall have an emergency plan which will ensure the effective implementation of any recall from the market of any such product, or batch thereof, that may be ordered by the Board or carried out in cooperation with the manufacturer or holder of the marketing authorisation for the medicinal product concerned.

10. The authorisation holder, in making a sale by wholesale to persons referred to in paragraph 4(*d*) and (*e*), shall enclose with the medicinal product a document that makes it possible for such persons to ascertain:

— the date on which the sale took place,

— the name and pharmaceutical form of the product supplied,

— the quantity of the product supplied, and

— the name and address of the supplier and consignor.

11. The authorisation holder shall, in respect of a medicinal product that has actually been placed on the market in the State and within the limits of his or her responsibility, ensure appropriate and continued supplies of that product to the persons referred to in paragraph 4(*d*) and (*e*), so that the needs of patients in the State in respect of such medicinal product are covered.

12. The authorisation holder, if he or she proposes to import from another EEA State a medicinal product in respect of which he or she is not the holder of the relevant marketing authorisation, or is not acting on behalf of such a person, shall notify the holder of the marketing authorisation concerned and the Board, of his or her intention to import the product.

13. The authorisation holder shall comply with the principles and guidelines of good distribution practice for medicinal products[8] published by the Commission under Article 84 of the 2001 Directive.

14. The authorisation holder shall, on being informed by the Board or by the holder of the marketing authorisation, that any batch of any medicinal product to which the wholesaler's authorisation relates, has been found not to conform as regards the provisions of the relevant marketing authorisation, or as regards the strength, quality or purity with the appropriate specification for that product, if so directed, immediately withhold such batch from sale or exportation, and if so directed by the Board, insofar as may be reasonably practicable, immediately withdraw from sale any supplies of that batch held by him or her and immediately recall all supplies already sold or distributed from that batch.

15. The authorisation holder shall, on being informed by the Board that a medicinal product to which the wholesaler's authorisation relates, has been found to give rise to concerns in regard to its safety or efficacy, if so directed by the Board, immediately withhold such product from sale, supply or exportation and insofar as may be reasonably practicable, immediately recall all supplies already sold or distributed by him or her.

16. The authorisation holder shall permit at all reasonable times such inspections, by officers of the Board, as may be required to satisfy the Board that the conditions of the authorisation are being complied with.

[8] OJ No. C 63, 01.03.1994, p.4.

17. (1) Where and insofar as the wholesaler's authorisation relates to an exempt sourced medicinal products, the authorisation holder shall only source such products—

(*a*) in response to an order, or in anticipation of an order, which satisfies the requirements of paragraph 2 of Schedule 1 to the Medicinal Products (Control of Placing on the Market) Regulations 2007; and

(*b*) where the conditions set out in subparagraphs (2) to (9) are complied with.

(2) The authorisation holder shall, in the case of each consignment of an exempt sourced medicinal product received by him or her, make, and keep available for inspection by officers of the Board, for a period of not less than five years, written records showing the following particulars—

(*a*) the name of the medicinal product, being the brand name or the common name, or the scientific name, and any name, if different, under which the particular medicinal product is to be sold or supplied in the State;

(*b*) the dosage form;

(*c*) the trading style or name of the manufacturer of the medicinal product;

(*d*) in respect of each active constituent of the medicinal product, any international non-proprietary name or the monograph name or, where that constituent does not have an international non-proprietary name, the accepted scientific name or any other name descriptive of the true nature of that constituent;

(*e*) the quantity of medicinal product which has been received;

(*f*) the batch number of the medicinal product which has been received; and

(*g*) the name and address of the manufacturer of that medicinal product in the form in which it was received and, if the person who supplied the medicinal product is not the manufacturer, the name and address of such supplier.

(3) Where the authorisation holder sells or supplies an exempt sourced medicinal product, he or she shall, in addition to those records mentioned in paragraph 8(1) and subparagraph (2), make and maintain written records relating to—

(*a*) the batch number of the batch of the product from which each sale or supply was made;

(*b*) details of any suspected adverse reaction to the product so sold or supplied of which he or she becomes aware; and

(*c*) details of any quality defect relating to the product so sold or supplied of which he or she becomes aware.

(4) The authorisation holder shall not issue any advertisement, catalogue, price list or circular relating to the exempt sourced medicinal product or make any representations in respect of that product.

(5) The authorisation holder shall inform the Board forthwith of any matter, including suspected adverse reactions and quality defects, coming to his or her attention, in respect of an exempt sourced medicinal product that has been sourced by him or her.

(6) The authorisation holder shall cease supplying an exempt sourced medicinal product if he or she has received a notice in writing from the Board directing that, as from a date specified in that notice, a particular product or class of products shall no longer be sourced or supplied.

(7) The authorisation holder shall, on being informed by the Board, or by the manufacturer or person who supplied the medicinal product to the holder of the authorisation, that the medicinal product can not be regarded either as a product which can safely be administered to human beings or as a product which is of satisfactory quality or efficacy for such administration, immediately withdraw any supplies of that product held by him or her and immediately recall all supplies already sold or distributed.

(8) With effect from the 1 January 2008, the authorisation holder shall, not later than seven days of his or her receipt of a consignment of an exempt sourced medicinal product, notify the Board of each such receipt. Each such notification shall include the particulars set out in subparagraph (2).

(9) With effect from the 1 January 2009, the notifications referred to in subparagraph (8) shall, except in exceptional circumstances, be communicated electronically to the Board and within a timeframe of two working days from the date of the receipt of each such consignment.

(10) In this paragraph—

'common name' means the international non-proprietary name, or, if one does not exist, the usual common name;

'international non-proprietary name' means the international non-proprietary name recommended by the World Health Organisation; and

'monograph name' means the name or approved synonym which appears at the head of a monograph in the current edition of the European Pharmacopoeia, the British Pharmacopoeia, or a foreign or international compendium of standards and 'current' in this definition means current at the time the notice is sent to the Board.

(Regulations 9(4), 12(6) and 13(3))

SCHEDULE 3

PROCEDURAL PROVISIONS RELATING TO PROPOSALS TO GRANT OTHERWISE THAN IN ACCORDANCE WITH THE APPLICATION, PROPOSALS TO REFUSE TO GRANT OR VARY, AND PROPOSALS TO SUSPEND, VARY OR REVOKE A WHOLESALER'S AUTHORISATION.

1. In this Schedule—

'authorisation' means a wholesaler's authorisation; and

'time allowed' means the period of 28 days or such extended period as the Board may in any particular case allow.

2. Subject to paragraph 6, if the Board proposes—

(*a*) not to grant an authorisation;

(*b*) to grant an authorisation other than in accordance with the application,

(*c*) to revoke, vary or suspend an authorisation; or

(*d*) not to vary an authorisation on the holder's application to vary,

the Board shall notify the applicant or authorisation holder accordingly.

3. Any notification given under paragraph 2 shall include—

(*a*) a statement of the proposals of the Board,

(*b*) a statement setting out in detail the reasons on which the said proposals are based, and

(*c*) a statement that the applicant or authorisation holder has the right to make representations to the Board in response to the notification.

4. A person to whom notification has been given under paragraph 2 may, within the time allowed after the notification was given, give notice to the Board of his or her wish to do so, and make representations to the Board with respect to the decision or proposal referred to in the notification.

5. The Board shall, after consideration of the representations, decide whether to grant the authorisation, revoke, vary or suspend the authorisation or confirm or alter its decision, as the case may be.

6. (1) Paragraph 2 shall not apply to the suspension of an authorisation where it appears to the Board that, in the interests of safety, it is necessary to suspend the authorisation with immediate effect for a period not exceeding 3 months.

(2) If, after the aforementioned suspension has taken effect, it appears to the Board that the authorisation should be further suspended or revoked, the Board shall proceed in accordance with the provisions of paragraphs 2 to 5.

L.S.

GIVEN under my Official Seal,
20 July 2007

MARY HARNEY
Minister for Health and Children

EXPLANATORY NOTE.

(This note is not part of the Instrument and does not purport to be a legal interpretation).

The main purpose of these Regulations is to implement TITLE VII of Directive 2001/83/EC (as amended by Directive 2004/27/EC) relating to the wholesale distribution of medicinal products for human use. The Regulations also consolidate and update the existing Regulations, which they replace.

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