



STATUTORY INSTRUMENTS.

S.I. No. 540 of 2007



MEDICINAL PRODUCTS (CONTROL OF PLACING ON THE
MARKET) REGULATIONS 2007

(Prn. A7/1461)

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MARKET) REGULATIONS 2007

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S.I. No. 540 of 2007

MEDICINAL PRODUCTS (CONTROL OF PLACING ON THE
MARKET) 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 by the European Communities (Amendment of the Irish Medicines Board Act 1995) Regulations 2007 (S.I. No. 542 of 2007) 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 Directive 2001/83/EC (as amended by Directive 2004/27/EC), hereby make the following regulations—

PART 1

GENERAL PROVISIONS

Citation.

1. These Regulations may be cited as the Medicinal Products (Control of Placing on the Market) Regulations 2007.

Commencement.

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

Interpretation.

3. (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;

‘Agency’ means the European Medicines Agency established by Regulation (EC) No. 726/2004/EC¹;

‘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 granted by the Board in accordance with these Regulations 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 granted by the Board in accordance with these Regulations in respect of a traditional herbal medicinal product;

¹OJ No. L.136, 30.4.2004, p. 1.

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

‘Commission’ means the Commission of the European Community;

‘Community’ means the European Community;

‘Community marketing authorisation’ means a marketing authorisation granted by the European Commission under Regulation (EEC) No. 2309/93² or Regulation (EC) No 726/2004;

‘Community Regulation on medicinal products for paediatric use’ means Regulation (EC) No. 1901/2006 of the European Parliament and of the Council on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No. 726/2004³, as amended by Regulation (EC) No. 1902/2006 of the European Parliament and of the Council amending Regulation 1901/2006 on medicinal products for paediatric use⁴;

‘2001 Directive’ means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use⁵ as amended by—

- (a) Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components⁶,
- (b) Commission Directive 2003/63/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use⁷,
- (c) Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use⁸, and
- (d) Directive 2004/27/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use⁹;

‘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 1993¹⁰;

‘EEA State’ means a State, which is a contracting party to the EEA Agreement;

²OJ No. L 214, 24.08.1993, p.1.

³OJ No. L 378, 27.12.2006, p.1.

⁴OJ No. L 378, 27.12.2006, p.20.

⁵OJ No. L 311, 28.11.2001, p.67.

⁶OJ No. L 33, 8.02.2003, p.30.

⁷OJ No. L 159, 27.06.2003, p.46.

⁸OJ No. L 136, 30.04.2004, p.85.

⁹OJ No. L 136, 30.4.2004, p.34.

¹⁰OJ No. L 1, 3.01.1994, p.572.

‘European Economic Area’ means the European Economic Area created by the EEA Agreement;

‘general sale’, in respect of a medicinal product, means that the product may be sold in a pharmacy and in any other outlet which is not a pharmacy and that it is a product to which the exemption referred to in subparagraph (ii) of section 32(2)(m) of the Act refers;

‘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;

‘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;

‘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);

‘marketing authorisation’ means an authorisation granted by the Board in accordance with these Regulations in respect of a medicinal product and includes an authorisation granted in accordance with Article 126a of the 2001 Directive, a product authorisation, a parallel import licence and an authorisation granted in accordance with Regulation 11;

‘medicinal product’ has the meaning assigned to it in section 1(1) of the Irish Medicines Board Act 1995, as amended by section 10(c) of the Irish Medicines Board (Miscellaneous Provisions) Act 2006;

‘medicinal product authorised for a paediatric indication’ means a medicinal product which is authorised for use in part or all of the paediatric population and in respect of which the details of the authorised indication are specified in the summary of the product characteristics;

‘Minister’ means the Minister for Health and Children;

‘paediatric use marketing authorisation’ means a marketing authorisation or a Community marketing authorisation granted in respect of a medicinal product for human use which is not protected by a supplementary protection certificate under Regulation (EEC) No 1768/92¹¹ or by a patent which qualifies for the granting of the supplementary protection certificate, covering exclusively therapeutic indications which are relevant for use in the paediatric population, or subsets thereof, including the appropriate strength, pharmaceutical form or route of administration for that product;

‘package leaflet’ means a leaflet containing information for the user which accompanies the medicinal product;

‘parallel import licence’ means a marketing authorisation or a certificate of traditional-use registration granted by the Board under these Regulations in respect of a medicinal product which is imported into the State from another EEA state in accordance with the rules of Community law relating to parallel imports;

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

‘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;

‘practitioner’ means a registered dentist or a registered medical practitioner;

‘product authorisation’ means an authorisation granted and in force in pursuance of the Medicinal Products (Licensing and Sale) Regulations 1998 (S.I. No. 142 of 1998);

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

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

‘registered nurse’ means a person registered in the register of nurses maintained by An Bord Altranais under section 27 of the Nurses Act 1985 (No. 18 of 1985);

‘Regulation (EC) No. 726/2004’ means Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency¹², read in conjunction with the Community Regulation on medicinal products for paediatric use;

‘relevant Community provisions’ means the provisions of—

(a) the 2001 Directive,

¹¹OJ No. L.182, 2.7.1992, p.1

¹²OJ No. L. 136, 30.04.2004, p.1.

- (b) Commission Regulation (EC) No. 540/95, laying down the arrangements for reporting suspected unexpected adverse reactions which are not serious, whether arising in the Community or in a third country, to medicinal products for human or veterinary use authorised in accordance with the provisions of Council Regulation (EEC) No. 2309/93¹³,
- (c) Regulation (EC) No. 141/2000, of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products¹⁴,
- (d) Regulation (EC) No. 847/2000, laying down the provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product and definitions of the concepts ‘similar medicinal product’ and ‘clinical superiority’¹⁵,
- (e) Commission Regulation (EC) No. 1084/2003, concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products granted by a competent authority of a Member State¹⁶,
- (f) Commission Regulation (EC) 1085/2003, concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93¹⁷,
- (g) Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and
- (h) the Community Regulation on medicinal products for paediatric use;

‘sale by way of wholesale dealing’ 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;

‘summary of product characteristics’ means the information required to accompany any application for a marketing authorisation or certificate of traditional-use registration by virtue of article 11 of the 2001 Directive;

‘third country’ means a country which is not an EEA State;

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

¹³OJ No. L.55, 11.3.1995, p.5.

¹⁴OJ No. L.103, 28.4.2000, p.1.

¹⁵OJ No. L.103, 28.04.2000, p.5.

¹⁶OJ No. L.159, 27.6.2003, p.1.

¹⁷OJ No. L.159, 27.6.2003, p.24.

‘wholesaler’s authorisation’ means an authorisation granted and in force in pursuance of Regulation 9 of the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (S.I. No. 538 of 2007).

(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,
- (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,
- (c) any reference in a paragraph to a subparagraph shall be construed as a reference to a subparagraph in that paragraph,
- (d) any reference to an application for the variation of a marketing authorisation, certificate of registration or certificate of traditional-use registration, includes a reference to a notification of such variation, and any reference to an applicant for a variation to such an authorisation or certificate includes reference to a person submitting such a notification.

(3) In these Regulations, where a requirement applies to a medicinal product that is the subject of a parallel import licence, such requirement shall be subject to the rules of Community law relating to parallel imports.

(4) A word or expression which is used in these Regulations and which is also used in the relevant Community provisions has, unless the context otherwise requires, the same meaning in these Regulations as it has in those provisions.

Scope of Regulations.

4. (1) The provisions of these Regulations shall apply to medicinal products for human use intended to be placed on the market in the State.

(2) In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a “medicinal product” and within the definition of a product covered by other Community legislation, the provisions of these Regulations shall apply.

Responsibility for functions under the EC Regulations and Directives.

5. (1) Subject to paragraph (2), the functions of the State and of the competent authority, under the relevant Community provisions shall be performed by the Board.

(2) Paragraph (1) shall not apply to those functions of a Member State referred to in—

- (a) Articles 10, 61.1, 62.2 and 65 of Regulation (EC) No. 726/2004;

- (b) Articles 5, 16h.2, 27.2, 33, 34.2, 69.2, 110, 121 and 127b of the 2001 Directive;
- (c) Regulation (EC) No. 141/2000, of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products; and
- (d) Articles 4, 39.2, 49.1 and 51 of the Community Regulation on medicinal products for paediatric use.

PART 2

AUTHORISATION AND CERTIFICATION FOR PLACING ON THE MARKET

Requirement for an authorisation or certificate to place a medicinal product on the market.

6. (1) Subject to the provisions of these Regulations, a person shall not place a medicinal product on the market unless such product is the subject of—

- (a) a marketing authorisation,
- (b) a Community marketing authorisation,
- (c) a certificate of registration, or
- (d) a certificate of traditional-use registration,

and, in each case, such authorisation or certificate is for the time being in force.

(2) A person shall not in the course of a business carried on by him, sell, supply, manufacture, or procure the sale, supply or manufacture or have in his possession a medicinal product unless he or she has reasonable cause to believe that the product was or is intended to be—

- (a) placed on the market in compliance with paragraph (1), or
- (b) placed on the market in another EEA State in accordance with the corresponding provisions as required by that State pursuant to the 2001 Directive.

(3) The provisions of paragraph (2) shall not apply in the case of a medicinal product intended for export to a third country.

(4) Schedule 1 shall have effect for the purpose of making certain exemptions from the provisions of this Regulation and for imposing certain obligations in connection with such exemptions.

Prohibition of marketing during period of data protection.

7. (1) A person shall not place a generic medicinal product on the market before the period of—

- (a) in a case where the application for the reference medicinal product was submitted before 30 October 2005 and the application was not in respect of a Community marketing authorisation, six years;
- (b) in a case where the application for the reference medicinal product was submitted on or after 30 October 2005 and where during the first eight years after the grant of the initial marketing authorisation of the reference medicinal product, the holder of that authorisation is granted an authorisation for a new therapeutic indication of significant clinical benefit as set out in the fourth subparagraph of Article 10.1 of the 2001 Directive or in Article 14.11 of Regulation (EEC) No. 2309/93, eleven years; and
- (c) in any other case, ten years,

has elapsed from the date of the initial marketing authorisation.

(2) A person shall not place a generic medicinal product on the market for a corresponding paediatric indication before the period of ten years has elapsed from the date of the initial paediatric use marketing authorisation.

(3) In this Regulation, the term “corresponding paediatric indication” means the authorised indication specified in the summary of product characteristics for the medicinal product to which the initial paediatric use marketing authorisation relates.

Immunity from liability in certain cases where an unauthorised medicinal product is used, or an authorised medicinal product is used for an unauthorised indication, on the temporary authorisation of the Minister.

8. (1) Nothing in these Regulations shall prevent the Minister from temporarily authorising the distribution of a medicinal product, which is not the subject of a marketing authorisation or Community marketing authorisation, in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation, any of which could cause harm.

(2) Subject to paragraphs (3) and (4), a person who is—

- (a) the holder of a marketing authorisation to which this paragraph applies,
- (b) a manufacturer of that product,
- (c) a person acting on behalf of any such marketing authorisation holder or manufacturer, and
- (d) a health professional,

shall not be subject to any civil or administrative liability for any consequences resulting from the use of the medicinal product in accordance with the recommendation or requirement of the Minister.

(3) The provisions of paragraph (2) shall apply where, in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation, any of which could cause harm, the Minister has recommended or required the use of—

- (a) a medicinal product which is not the subject of a marketing authorisation or Community marketing authorisation; or
- (b) a medicinal product which is the subject of such a marketing authorisation for a therapeutic indication that is not included in the summary of product characteristics under that authorisation.

(4) Liability for defective products, as provided for by Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States, concerning the liability for defective products¹⁸, shall not be affected by paragraph (2).

(5) In this Regulation, ‘health professional’ means a person of any of the following classes—

- (i) registered medical practitioners,
- (ii) registered dentists,
- (iii) pharmacists,
- (iv) registered nurses,
- (v) a member of any other class of health professional designated for the purpose by the Minister.

Application for the grant, renewal or variation of authorisations and certificates.

9. (1) Every application for the grant, renewal or variation of a marketing authorisation, a certificate of registration or a certificate of traditional-use registration (hereinafter in this Regulation referred to as an application), shall—

- (a) be made in writing to the Board;
- (b) be signed by or on behalf of the applicant, whether in ink or by means of an electronic signature; and
- (c) subject to the rules of Community law relating to parallel imports, be made in accordance with the relevant Community provisions as are applicable to the application, including but not limited to the relevant provisions of Chapters 1, 2 and 2a of Title III of the 2001 Directive, as may be amended from time to time.

¹⁸OJ No. L.210, 7.8.1985, p.29 (as last amended by Directive 1999/34/EC), and as implemented by the Liability for Defective Products Act 1991 (No. 28 of 1991) as amended by the European Communities (Liability for Defective Products) Regulations 2000 (S.I. No. 401 of 2000).

(2) In the case of every such application, the applicant shall comply with so much of the relevant Community provisions as impose obligations on applicants as are applicable to the application and to the consideration of it by the Board.

(3) Every application shall include a statement indicating whether the medicinal product is one that should be available—

— only on medical prescription,

— only from a pharmacy, or

— on general sale.

(4) Every application shall, unless the Board otherwise directs, be accompanied by any fee which may be payable in connection with that application.

(5) In the case of an application, the number of copies to be supplied shall be as determined by the Board from time to time and each such application and of any accompanying material shall be supplied to the Board in the English or in the Irish language.

(6) The applicant for the grant or renewal of a marketing authorisation, a certificate of registration and a certificate of traditional-use registration shall be established in an EEA State and shall be responsible for the accuracy of any documents and data submitted in support of any such application.

(7) An application for the renewal of a marketing authorisation, certificate of registration or certificate of traditional use registration (including any authorisation or certificate granted under the Medicinal Products (Licensing and Sale) Regulations 1998), shall be made not later than 6 months before the date on which the said authorisation or certificate expires.

(8) For the purposes of Article 10.1 of the 2001 Directive, the period of 8 years, during which the reference medicinal product must have been authorised, shall not apply if the application for the reference medicinal product was submitted before 30 October 2005.

(9) Where by reason of paragraph (8) the period of 8 years does not apply, the applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he or she can demonstrate that the medicinal product is a generic of a reference medicinal product, which has been authorised in an EEA State for not less than 6 years.

(10) The fourth subparagraph of Article 10.1 of the 2001 Directive shall not apply if the application for the initial authorisation of the reference medicinal product was submitted before the 30 October 2005.

Consideration by the Board of applications in connection with authorisations and certificates, including their grant, refusal, renewal, variation and duration.

10. (1) The Board shall—

- (a) consider every application for the grant, renewal or variation by it of a marketing authorisation, certificate of registration or certificate of traditional-use registration, in accordance with the relevant Community provisions and where applicable the rules of Community law relating to parallel imports, and
- (b) grant, renew or vary, or refuse to grant, renew or vary the marketing authorisation, certificate of registration or certificate of traditional-use registration, in accordance with those provisions and where applicable the rules of Community law relating to parallel imports.

(2) The Board shall make its decision to grant or to revoke a marketing authorisation, certificate of registration or certificate of traditional-use registration publicly available.

(3) Subject to the following provisions of this Regulation, a marketing authorisation (other than a parallel import licence), a certificate of registration or a certificate of traditional-use registration, shall, unless previously revoked, be valid for the period specified in it (being a period not exceeding five years) beginning with the date on which it is granted, but where an application for the renewal of such an authorisation or certificate is made in accordance with Article 24.2 of the 2001 Directive, the authorisation or certificate shall remain in force pending the decision of the Board on that application.

(4) A parallel import licence shall, unless previously renewed or revoked, be valid for the period specified in it, but, where an application to renew it is made in accordance with regulation 9(7), it shall remain in force pending the decision of the Board on that application.

(5) Once a marketing authorisation (other than a parallel import licence), a certificate of registration or a certificate of traditional-use registration, is renewed following the coming into force of these Regulations, the authorisation shall be valid for an unlimited period, unless the Board decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal in accordance with paragraph (3).

(6) Where a medicinal product to which a marketing authorisation (other than a parallel import licence), a certificate of registration or a certificate of traditional-use registration, relates has not actually been placed on the market in the State within the period of three years from the date on which the said authorisation or certificate was granted, or from the date on which these Regulations come into force (whichever is the later date), the authorisation or certificate concerned shall cease to be valid.

(7) Where a medicinal product to which a marketing authorisation (other than a parallel import licence), a certificate of registration or a certificate of traditional-use registration relates, has previously been placed on the market in

the State and is no longer actually present on the market for a period of three consecutive years from the date on which the said authorisation or certificate was granted, or from the date on which these Regulations come into force (whichever is the later date), the marketing authorisation or certificate concerned shall cease to be valid.

(8) The Board may, in exceptional circumstances and on grounds of public health, grant exemptions from paragraphs (6) and (7). In all such cases, the exemptions shall be duly justified.

(9) The provisions of Schedule 2 shall have effect where the Board—

- (a) proposes to grant a marketing authorisation, certificate of registration or certificate of traditional-use registration, in accordance with the application, but subject to the carrying out of certain obligations by the holder of the authorisation or of the certificate as the case may be,
- (b) proposes to grant a marketing authorisation, certificate of registration or certificate of traditional-use registration, otherwise than in accordance with the application, or
- (c) proposes to refuse to grant a marketing authorisation, certificate of registration or certificate of traditional-use registration.

(10) Where the Board—

- (a) grants a marketing authorisation, certificate of registration or certificate of traditional-use registration, in accordance with the application, but subject to the carrying out of certain obligations by the holder of the authorisation or of the certificate as the case may be,
- (b) grants a marketing authorisation, certificate of registration or certificate of traditional-use registration, otherwise than in accordance with the application, or
- (c) refuses to grant a marketing authorisation, certificate of registration or certificate of traditional-use registration,

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

Authorisation of homeopathic medicinal products under national rules.

11. (1) Notwithstanding the provisions of Regulations 9 and 10 insofar as those provisions relate to the requirements for pre-clinical tests and clinical trials, the Board may grant a marketing authorisation in respect of a homeopathic medicinal product other than a product referred to in Article 14.1 of the 2001 Directive.

(2) For the purposes of obtaining an authorisation in accordance with this Regulation and subject to paragraph (3), the applicant shall demonstrate to the satisfaction of the Board—

- (a) that the product is a homeopathic medicinal product which conforms with the principles and characteristics of homeopathy as practised in the State;
- (b) that the indication sought is appropriate to such a homeopathic medicinal product;
- (c) that any such indication shall be suitable for use without the intervention of a registered medical practitioner for diagnostic purposes or for prescription or for the monitoring of treatment;
- (d) that the efficacy of the product shall be established on the basis of evidence that the particular class of homeopathic medicinal product has been in use in the State as a homeopathic treatment for the indication sought; and
- (e) that the safety of the homeopathic medicinal product has been established in the manner set out in paragraph (3).

(3) For the purpose of this Regulation and subject to subparagraph (4), the safety of the homeopathic medicinal product shall be demonstrated—

- (a) by reference to relevant published literature or original data having regard to the proposed route of administration and the dilution involved; or
- (b) in the case of stocks derived from substances commonly used in food, by means of a statement setting out the homeopathic nature of the product and the absence of any change to the route of exposure for the substance concerned; or
- (c) in the case of an active principle used in allopathic medicinal products, by establishing that the dilution of the stocks is at least 1 in 10,000 of the mother tincture or not more than one hundredth of the smallest dose of the said active principle as used in allopathy; or
- (d) by establishing that the medicinal product contains not more than one part per 10,000 of the mother tincture.

(4) In regard to the active principles referred to in subparagraphs (3)(c) and (d), the Board may refuse to grant an authorisation where it is satisfied that the active principle concerned is toxic and as such would present concerns in regard to the safety of the product. For the purposes of this subparagraph, the Board may publish and update from time to time a list of the substances that it considers to be in this category.

(5) A homeopathic medicinal product that is placed on the market on foot of a marketing authorisation granted in accordance with this Regulation shall, in addition to compliance with the requirements of Regulation 16 (relating to labelling and package leaflets), be presented in such a manner as to show—

- (a) that the product is a homeopathic medicinal product in respect of which an authorisation has been granted in accordance with this Regulation;
- (b) that any evidence of efficacy on the part of the product has not been based on the outcome of clinical trials;
- (c) that use of the product is only intended for the symptomatic relief of the condition to which the indication specified relates; and
- (d) that the user is advised to consult a doctor or other healthcare professional if the symptoms persist.

Classification of medicinal products.

12. (1) Subject to the provisions of this Regulation, every marketing authorisation, certificate of registration or certificate of traditional-use registration granted or renewed by the Board following the coming into force of these Regulations, shall be granted subject to the condition that the medicinal product concerned is to be available on one or more of the following bases—

- (a) only on medical prescription, in which case it shall be assigned one of the following sub-categories-
 - (i) only on medical prescription for non-renewable supply; or
 - (ii) on medical prescription for renewable supply;

or
- (b) not subject to medical prescription, in which case it shall be assigned one of the following sub-categories-
 - (i) only from a pharmacy; or
 - (ii) on general sale.

(2) Paragraph 1(a) applies to any medicinal product which—

- (a) is likely to present a danger either directly or indirectly to human health, even when used correctly, if used without the supervision of a practitioner; or
- (b) is frequently and to a wide extent used incorrectly, and as a result is likely to present a direct or indirect danger to human health; or
- (c) contains substances or preparations of substances the activities of which, or adverse reactions of which, require further investigation; or
- (d) is normally prescribed by a practitioner to be administered parenterally.

- (3) In considering whether paragraph (2) applies to a medicinal product, the Board shall take into account whether the product—
- (a) contains a substance which is listed in any of Schedules I, II or IV to the Single Convention on Narcotic Drugs (where the product is not a preparation listed in Schedule III of that Convention); or
 - (b) contains a substance which is listed in any of Schedules I to IV to the Convention on Psychotropic Substances (where the product is not a preparation which may be exempted from measures of control in accordance with paragraphs 2 and 3 of article 3 of that Convention); or
 - (c) is likely, if incorrectly used—
 - (i) to present a substantial risk of medicinal abuse, or
 - (ii) to lead to addiction, or
 - (iii) to be used for illegal purposes; or
 - (d) contains a substance which, by reason of its novelty or properties, could, as a precautionary measure, be considered as falling under paragraph (c) above; or
 - (e) by reason of its pharmaceutical characteristics or novelty, or in the interests of public health, is reserved for treatments which can only be followed in a hospital; or
 - (f) is used in the treatment of conditions which must be diagnosed in a hospital or in an institution with special diagnostic facilities, although administration and subsequent supervision may be carried out elsewhere; or
 - (g) is intended for outpatients but its use may produce very serious adverse reactions requiring a prescription drawn up as required by a specialist and special supervision throughout the treatment.
- (4) Paragraph (1)(a) shall not apply in relation to any medicinal product if the Board so determines having regard to—
- (a) the maximum single dose;
 - (b) the maximum daily dose;
 - (c) the strength of the product;
 - (d) its pharmaceutical form;
 - (e) its packaging; or

(f) any such other circumstances relating to its use as the Board may specify in its determination.

(5) In the determination of which of the sub-categories referred to in paragraphs 1(a)(i) and 1(a)(ii) should be assigned to a particular medicinal product, the Board shall have regard to the reasonable needs for patients to have access to repeat supplies of the product which may be prescribed by their practitioner for the treatment of an ongoing, intermittent or recurring condition and in circumstances where it is safe to do so and where the practitioner concerned has not directed that such repeat supply shall not be made.

(6) In the specification of the sub-category referred to in paragraph (1)(b)(ii), the Board shall have regard to the nature and purpose of the medicinal product and be satisfied that the product concerned can with reasonable safety be sold or supplied otherwise than by, or under the supervision of a pharmacist.

(7) Where prior to the coming into force of these Regulations, a medicinal product is the subject of a marketing authorisation or certificate of registration and that authorisation or certificate contains a statement that it is to be available on one or more of the following bases—

- (a) only on prescription;
- (b) only from a pharmacy; or
- (c) on general sale,

it is a condition of the marketing authorisation or certificate of registration that, from the coming into force of these Regulations, the product concerned is to be available only on that basis or, as the case may be, on those bases.

(8) The Board shall draw up and publish a list of medicinal products that are the subject of classifications by virtue of paragraph (1) and shall specify the particular sub-category for each product in that list as set out in that paragraph. Such list shall be updated and published, at least annually.

(9) In this Regulation—

‘Single Convention on Narcotic Drugs’ means the United Nations Single Convention on Narcotic Drugs 1961, as amended by the Protocol Amending the Single Convention on Narcotic Drugs 1961, as acceded to by Ireland on 16th December 1980;

‘Convention on Psychotropic Substances’ means the United Nations Convention on Psychotropic Substances 1971 as acceded to by Ireland on 7th August 1992.

Urgent safety restrictions.

13. (1) The Board may, subject to and in accordance with the relevant Community provisions, impose an urgent safety restriction on the holder of a marketing authorisation, certificate of registration or certificate of traditional-use registration.

(2) Where the Board, imposes an urgent safety restriction in accordance with paragraph (1), the holder of the authorisation or certificate shall—

- (a) implement the restriction within a period specified by the Board; and
- (b) apply to vary the authorisation or certificate to take account of that safety restriction immediately and in any event not later than 15 days after the restriction was imposed.

(3) Where the Commission, in respect of a Community marketing authorisation, imposes an urgent safety restriction under Commission Regulation (EC) No. 1085/2003, the holder of the marketing authorisation shall—

- (a) implement the restriction within the period specified by the Commission; and
- (b) apply to vary the authorisation to take account of that safety restriction immediately and in any event not later than 15 days after the restriction was imposed

Revocation, suspension, or variation of an authorisation or certificate or the suspension of the use or marketing of medicinal products.

14. (1) The Board may and, where appropriate, shall, subject to and in accordance with the relevant Community provisions, revoke, suspend or vary a marketing authorisation, a certificate of registration or a certificate of traditional use registration.

(2) The Board may, and where appropriate shall, subject to paragraph (3) and subject to and in accordance with the relevant Community provisions, by notice in writing to the holder of a marketing authorisation, certificate of registration or certificate of traditional-use registration, forthwith or from a date specified in the notice, suspend the use, supply or marketing within the State of the medicinal product to which the authorisation or certificate relates, for a period specified in the notice.

(3) In any case where the relevant Community provisions permit or require the suspension of the use, supply or marketing of a medicinal product until some decision or similar action is taken by the Community, the Board may, instead of specifying a period in the notice, provide that the suspension is to apply until further notice.

(4) Where the Board, in accordance with paragraph (3) includes a provision that the suspension is to apply until further notice, it shall, where the effect of the Community decision or action is that the medicinal product may continue to be used or, as the case may be, marketed in the State, promptly give the holder of the authorisation or certificate written notice revoking the suspension forthwith or from such date specified in the notice as to comply with that decision or action.

(5) Where, under the preceding provisions of this Regulation or the provisions of Regulation (EC) No 726/2004, the Board or the Commission revokes

or suspends a marketing authorisation or Community marketing authorisation or the Board revokes or suspends a certificate of registration or certificate of traditional-use registration, or where the Board suspends the use, supply or placing on the market of a medicinal product, or where the relevant Community provisions so permit or require, the Board may and where appropriate, shall give written notice to the person who is or, immediately before its revocation or suspension, was the holder of the authorisation or certificate, requiring him or her to take all reasonable practicable steps to—

- (a) inform wholesalers, pharmacies, retailers, practitioners, patients and others who may be in possession of the relevant products, of the revocation or suspension, the reasons for it, and the action, if any, to be taken to restrict or prevent further use, supply or marketing;
 - (b) withdraw from the market in the State and recover possession of such products within the time and for the period specified in the notice.
- (6) The Board may require the holder of the marketing authorisation, certificate of registration or certificate of traditional-use registration, to withdraw from the market in the State specified batches only of a medicinal product to which a notice under paragraph (5) applies.
- (7) A person shall not sell, supply or place on the market or procure the sale, supply or placing on the market of a medicinal product where the use, supply or marketing of such product has been suspended in accordance with this Regulation or Regulation (EC) No. 726/2004.
- (8) A person who is or, immediately before its revocation or suspension, was the holder of a marketing authorisation, Community marketing authorisation, certificate of registration or certificate of traditional-use registration, shall comply with the notice given to him or her under paragraph (5).
- (9) The provisions of Schedule 2 shall have effect where the Board—
- (a) proposes to suspend or revoke a marketing authorisation, certificate of registration or certificate of traditional-use registration, in accordance with this Regulation;
 - (b) proposes to vary a marketing authorisation, certificate of registration or certificate of traditional-use registration, otherwise than in accordance with an application by the holder of the authorisation or certificate, as the case may be;
 - (c) proposes to make a marketing authorisation, certificate of registration or certificate of traditional-use registration, conditional on the carrying out of certain obligations by the holder of the authorisation or certificate, as the case may be, or
 - (d) proposes to refuse to vary a marketing authorisation, certificate of registration or certificate of traditional-use registration, after consideration of the application made by the holder of the authorisation or certificate, as the case may be.

(10) Where the Board—

- (a) suspends or revokes a marketing authorisation, certificate of registration or certificate of traditional-use registration, in accordance with this Regulation,
- (b) varies a marketing authorisation, certificate of registration or certificate of traditional-use registration, otherwise than in accordance with an application by the holder of the authorisation or certificate, as the case may be,
- (c) proposes to make a marketing authorisation, certificate of registration or certificate of traditional-use registration, conditional on the carrying out of certain obligations by the holder of the authorisation or certificate, as the case may be, or
- (d) proposes to refuse to vary a marketing authorisation, certificate of registration or certificate of traditional-use registration, after consideration of the application made by the holder of the authorisation or certificate, as the case may be,

the Board shall give the applicant or the holder of the authorisation or certificate a notice in writing stating in detail the reasons on which its decision is based.

PART 3

OBLIGATIONS OF PERSONS PLACING MEDICINAL PRODUCTS ON THE MARKET

General obligations.

15. (1) The holder of a marketing authorisation, certificate of registration or certificate of traditional-use registration shall be responsible for placing the relevant medicinal product on the market and the designation of a representative shall not relieve the said holder of his responsibilities;

(2) Every holder of a marketing authorisation, certificate of registration or certificate of traditional-use registration, shall—

- (a) comply with all the obligations which relate to him or her by virtue of the relevant Community provisions (apart from Regulation (EC) No. 726/2004) including, in particular, obligations relating to providing or updating information, to making changes, to applying to vary his authorisation or certificate, to pharmacovigilance, and to labelling and package leaflets;
- (b) except in the case of the holder of a certificate of registration, maintain a record of reports of which he or she is aware of suspected adverse reactions in accordance with the relevant Community provisions, which shall be available for inspection by a person authorised by the Board, who may take copies of the record and, if the Board so directs, the holder shall furnish the Board with a copy of any such

reports of which he or she has a record or of which he or she is or subsequently becomes aware;

- (c) keep such documents as will facilitate the withdrawal or recall from sale or supply of any medicinal product to which the authorisation or certificate relates.

(3) Where, by or under any provision of the relevant Community provisions or of these regulations, a person is required to provide any information or furnish any document to the Board and no time is specified in that provision within which that obligation is to be performed, it shall be performed within such time as may be specified in a written notice served on that person by the Board.

(4) The holder of a Community marketing authorisation shall provide the Agency with any data requested pursuant to the final paragraph of Article 13.4 or of Article 26 of Regulation (EC) 726/2004, within the time specified in the request, or if no time is so specified, the data requested shall be provided promptly.

(5) The holder of a marketing authorisation, certificate of registration or certificate of traditional-use registration, granted or renewed shall be established in an EEA State and shall be responsible for the accuracy of any documents and data submitted in connection with such authorisation or certificate.

(6) The holder of a marketing authorisation, certificate of registration or certificate of traditional-use registration shall promptly—

- (a) update information concerning the medicinal product or any connected matter as required by Articles 8.3, 15 or 16c of the 2001 Directive;
- (b) take any steps reasonably necessary to take account of scientific and technical progress for the purposes of making any changes or amendments as required by the first paragraph of Article 23 of the 2001 Directive;
- (c) introduce any changes or make any amendments that may be required in accordance with those Articles referred to in subparagraphs (a) and (b) or paragraphs 3.2(9), 3.2.1.2(c) and 3.2.2.4(c) of Part I of Annex I to the 2001 Directive;
- (d) provide information to the Board as required by the third or fourth paragraphs of Article 23 of the 2001 Directive;
- (e) submit any application to the Board or the Community to make any changes or variations as required by Article 23 of the 2001 Directive;
- (f) submit any data requested by the Board pursuant to the final paragraph of Article 23 or of Article 23a of the 2001 Directive and where the Board has served a written notice on the holder in relation to any such request, the data shall be submitted within such time as may be specified in that notice;

- (g) after an authorisation or certificate has been granted to him, inform the Board of the date of actual placing on the market, taking into account the various presentations to which the authorisation or certificate relates, as required by the first paragraph of Article 23a of the 2001 Directive;
- (h) notify the Board if the product ceases to be placed on the market, either temporarily or permanently as required by the second paragraph of Article 23a of the 2001 Directive. Such notification shall, except in exceptional circumstances, be made no less than 2 months before the interruption of the placing on the market of the product;
- (i) if the circumstances referred to in either of paragraphs (6) or (7) of Regulation 10 have been met, inform the Board on the expiry of said three year period, or not later than two months after the date on which the said period has expired, that the medicinal product concerned has not actually been placed on the market or, as the case may be, has not actually been present on the market, during the said three year period;
- (j) inform the Board of any defect that could result in a recall or abnormal restriction on supply of the medicinal product concerned.

(7) Subparagraphs (g), (h) and (i) of paragraph (6) shall not apply to the holder of a parallel import licence.

Labelling and package leaflets.

16. (1) Without prejudice to the provisions of Regulation 17 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003), a person responsible for placing a medicinal product on the market, which is the subject of a Community marketing authorisation or of a marketing authorisation, certificate of registration or certificate of traditional-use registration, shall not sell, supply or procure the sale or supply of such product unless—

- (a) the labelling and any package leaflet accompanying the product are in compliance with Title V of the 2001 Directive; and
- (b) except where all the information required to be included in the said package leaflet is directly conveyed on the outer packaging or immediate packaging of the product, the packaging contains a package leaflet in compliance with Title V of the 2001 Directive.

(2) A person, other than the person responsible for placing a medicinal product on the market, shall not, in the course of a business conducted by him, sell, supply, offer or keep for sale or supply or procure the sale or supply of such product unless the product meets the requirements of this Regulation.

(3) In this Regulation the reference to “Title V of the 2001 Directive” shall, in the case of a traditional herbal medicinal product, include the requirements of Article 16g.2 of the 2001 Directive.

Pharmacovigilance.

17. (1) A person responsible for placing a medicinal product on the market, which is the subject of a Community marketing authorisation or of a marketing authorisation, or certificate of traditional-use registration, shall—

- (a) have permanently and continuously at his disposal an appropriately qualified person responsible for pharmacovigilance, as required by Title IX of the 2001 Directive or Chapter 3 of Title II of Regulation (EC) No. 726/2004, who shall reside in the Community;
- (b) make and retain a detailed account of any suspected adverse reaction as required by Title IX of the 2001 Directive or Chapter 3 of Title II of Regulation (EC) No. 726/2004;
- (c) promptly report to the Board any suspected serious adverse reaction, or submit to the Board any records of suspected serious adverse reactions, as required by Title IX of the 2001 Directive or Chapter 3 of Title II of Regulation (EC) No. 726/2004. Such report shall be made to the Board no later than 15 days following receipt of the information concerned;
- (d) promptly report to the Board, and where appropriate to the Agency, any suspected serious unexpected adverse reaction and any suspected transmission via a medicinal product of any infectious agent occurring in the territory of a third country. Such report shall be made to the Board and where appropriate to the Agency, no later than 15 days following receipt of the information concerned;
- (e) except where other requirements are laid down as a condition for the granting of the authorisation or certificate, or subsequently, submit to the Board, and where appropriate to the Agency, reports of adverse reactions in the form of a periodic safety update report. Such report shall be submitted immediately upon request or at least every six months after the date of grant of the authorisation or certificate and until the placing on the market. Such reports shall also be submitted immediately upon request or at least every six months during the first two years following the initial placing on the market and once a year for the following two years. Thereafter, the reports shall be submitted at three yearly intervals or immediately upon request. The periodic safety update reports shall include a scientific evaluation of the risk-benefit balance of the medicinal product; and
- (f) in the case of a medicinal product which is the subject of a Community marketing authorisation, at the request of the Agency given within the period of five years following the initial placing of the said product on the market in the Community, arrange for specific pharmacovigilance data to be collected from targeted groups of patients. Such data shall be collated, assessed and submitted to the Agency for evaluation.

(2) A person employed or engaged as an appropriately qualified person responsible for pharmacovigilance for the purpose of Title IX of the 2001 Directive or Chapter 3 of Title II of Regulation (EC) No. 726/2004 shall—

- (a) establish and maintain a system for collecting and collating information about suspected adverse reactions;
- (b) prepare for the Board a report on any such reactions, including a periodic safety update report and a scientific evaluation of the risk-benefit balance of the medicinal product, as required by Title IX of the 2001 Directive or Chapter 3 of Title II of Regulation (EC) No. 726/2004;
- (c) ensure that a request from the Board for the provision of additional information for the evaluation of the benefits and risks afforded by a medicinal product is answered fully and promptly, including the provision of information about the volume of sales or of prescriptions for the medicinal product concerned; and
- (d) provide to the Board any other information relevant to the evaluation of the benefits and risks afforded by a medicinal product, including appropriate information on post authorisation safety studies.

(3) Where a report is required to be made to the Board under this Regulation, such report shall, except in exceptional circumstances, be communicated electronically to the Board and shall be in the form of a report prepared and presented in accordance with guidelines published under Article 106.1 of the 2001 Directive.

Information on pharmacovigilance concerns for the general public.

18. (1) A person who is the holder of a Community marketing authorisation or of a marketing authorisation, or certificate of traditional-use registration, in respect of a medicinal product, shall not communicate information relating to pharmacovigilance concerns about that product to the general public without giving prior or simultaneous notification to the Board, or in the case of a Community marketing authorisation, to the Agency.

(2) In any case where information of the nature referred to in paragraph (1) is communicated by any such person, the said information shall be presented objectively and shall not be misleading.

Obligation to ensure that supplies continue to be available to meet the needs of patients.

19. A person who is the holder of a Community marketing authorisation, marketing authorisation, certificate of registration or certificate of traditional-use registration, and any person acting on behalf of such a person, in respect of a medicinal product actually placed on the market in the State, and within the limits of his responsibility, shall ensure appropriate and continued supplies of that product to pharmacies and other persons authorised to supply such products, so that the needs of patients in the State in respect of any such medicinal product are catered for.

PART 4

AMENDMENT OF MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) REGULATIONS 2003

Interpretation.

20. Regulation 4 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003), as amended by the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2005 (S.I. No. 510 of 2005), is hereby amended by—

(a) the insertion in paragraph (1) of the following definitions—

“ ‘certificate of traditional-use registration’, ‘Community marketing authorisation’ and ‘parallel import licence’ have the meaning assigned to them by Regulation 3(1) of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007);

‘marketing authorisation’ means an authorisation granted by the Board in accordance with the Medicinal Products (Control of Placing on the Market) Regulations 2007 in respect of a medicinal product and includes a certificate of traditional-use registration and a parallel import licence;”;

(b) by the insertion of the following paragraph after paragraph (2)—

“(3) In Regulations 5(5) and 15(1), the reference to a product authorisation shall include reference to a Community marketing authorisation and a marketing authorisation.”.

Medicinal products subject to prescription control.

21. Regulation 5 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003), as amended by the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2005 (S.I. No. 510 of 2005), is hereby amended by—

(a) the substitution of paragraph (1) by the following—

“(1) Subject to the provisions of these Regulations, a person shall not supply a medicinal product of any of the following classes except in accordance with a prescription, namely—

(a) any medicinal product in respect of which a Community marketing authorisation or marketing authorisation has been granted, and such authorisation contains a statement that the product is to be available only on medical prescription;

(b) any medicinal product, in respect of which no Community marketing authorisation or marketing authorisation has been granted, which consists of or contains a substance

specified in column 1 of the First Schedule or a substance which is a new chemical molecule;

(c) any medicinal product which is intended for parenteral administration;

(d) any medicinal product that on administration emits radiation, or contains or generates any substance which emits radiation, in order that radiation may be used;

and the supply shall be made by a person keeping open shop for the dispensing or compounding of medical prescriptions under the Pharmacy Acts 1875 to 1977 and by or under the personal supervision of an authorised person.”;

(b) the substitution in paragraph (2) of the words “paragraph (1)(a)” by the words “paragraphs (1)(a) and (b)”;

(c) the deletion of paragraph (4).

Prescription status of certain medicinal products including those that are the subject of authorisations or certificates granted prior to the coming into force of these Regulations.

22. Regulation 7 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003, as amended by the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2005, is hereby amended by—

(a) the substitution in each of paragraphs (2)(h) and (4) of the words “regulation 5(1)(b) or (c)” by the words “regulation 5(1)(c) or (d)”;

(b) the substitution of the following paragraph for paragraph (6)—

“(6) The prescription in the case of a medicinal product which consists of or contains a substance specified in Part C of the First Schedule or is a medicinal product to which Regulation 5(1)(d) refers, shall not be dispensed except in a hospital.”;

(c) the insertion of the following paragraph after paragraph (9)—

“(10) In this Regulation—

(a) any medicinal product which is the subject of a marketing authorisation granted after the coming into force of these Regulations and such authorisation contains a statement that the product is to be available—

(i) only on medical prescription for non-renewable supply, such product shall be treated as being a medicinal product in Part A of the First Schedule, or

- (ii) only on medical prescription for renewable supply, such product shall be treated as being a medicinal product in Part B of the First Schedule;
- (b) any medicinal product which is the subject of a Community marketing authorisation granted after the coming into force of these Regulations and such authorisation contains a statement that the product is to be available only on medical prescription, shall be treated as being a medicinal product in Part B of the First Schedule unless the product consists of or contains a substance specified in Part A of the said Schedule and in which case the said product shall be treated as being a medicinal product in Part A of that Schedule;
- (c) any medicinal product which prior to the coming into force of these Regulations is the subject of a Community marketing authorisation or product authorisation and such authorisation contains a statement that the product is to be available only on medical prescription, such product shall—
 - (i) where it consists of or contains a substance specified in Part A of the First Schedule, be treated as being a medicinal product in Part A of that Schedule;
 - (ii) where it does not consist of or contain a substance specified in Part A of the First Schedule, be treated as being a medicinal product in Part B of that Schedule;
- (d) any medicinal product which prior to the coming into force of these Regulations is the subject of a product authorisation and which consists of or contains a new chemical molecule, shall be treated as being a medicinal product in Part A of that Schedule.”.

Exemptions in respect of the supply and administration of a medicinal product on the temporary authorisation of the Minister in certain emergency situations.

23. Regulation 20 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003, as amended by the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2005, is hereby amended by the insertion of the following paragraph after paragraph (8)—

“(9) The provisions of these Regulations shall not apply—

- (a) to the supply of a medicinal product to which Regulation 8 of the Medicinal Products (Control of Placing on the Market) Regulations 2007 applies in the emergency circumstances, referred to in paragraph (3) thereof, or
- (b) to the supply of any other medicinal product for use in such emergency circumstances,

where the Minister has recommended or required the use of the said medicinal product.”.

Restatement of Regulation 20A as it applies to the Seventh Schedule.

24. Regulation 20A of the Medicinal Products (Prescription and Control of Supply) Regulations 2003, as inserted by Regulation 3(*n*) of the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2005, is hereby substituted as follows—

“20A. The Seventh Schedule, as contained in the Schedule to the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2005, is inserted after the Sixth Schedule.”.

PART 5

TRANSITIONAL ARRANGEMENTS AND REVOCATIONS

Transitional provisions.

25. (1) Any product authorisation or certificate of registration granted by the Board in pursuance of the Medicinal Products (Licensing and Sale) Regulations 1998 (as amended) and in force on the coming into force of these Regulations, shall continue in force until the date of expiry of such authorisation or certificate, as if it were a marketing authorisation or certificate of registration granted under these Regulations.

(2) An application made in respect of the grant or renewal of a product authorisation or certificate of registration under the Medicinal Products (Licensing and Sale) Regulations 1998, 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 9 of these Regulations.

(3) The provisions of these Regulations shall not apply, insofar as they relate to the labelling and package leaflets of medicinal products in respect of which—

- (a) a product authorisation, Community marketing authorisation or certificate of registration is in force on the date of coming into force of these Regulations, or
- (b) an application for a product authorisation or certificate of registration has been made before the date of coming into force of these Regulations,

until 30 October 2010. During such period, and except as may be provided in the relevant marketing authorisation or certificate of registration, the provisions of the Medical Preparations (Labelling and Package Leaflets) Regulations 1993 (S.I. No. 71 of 1993) (as amended) shall apply only to such products.

- (4) (a) The provisions of these Regulations shall not apply until 30 April 2011 to traditional herbal medicinal products that were on the market in the State on the coming into force of these Regulations.

- (b) Notwithstanding clause (a) of this subparagraph and with a view to ensuring that certificates of traditional-use registration are held by the 30 April 2011, the Board may establish and publish dates by which applications in accordance with these Regulations, for such certificates shall be made in respect of such products or classes of such products as the Board may specify, and the Board shall consider each such application as provided for in these Regulations.
- (5) (a) The provisions of these Regulations shall not apply until 30 April 2011 to homeopathic medicinal products to which Regulation 11 applies and which were on the market in the State on the coming into force of these Regulations.
- (b) Notwithstanding clause (a) of this subparagraph and with a view to ensuring that marketing authorisations are held by the 30 April 2011, the Board may establish and publish dates by which applications in accordance with these Regulations, for such authorisations shall be made in respect of such products or classes of such products as the Board may specify, and the Board shall consider each such application as provided for in these Regulations.

Revocation.

26. (1) The Medicinal Products (Licensing and Sale) Regulations 1998 (as amended) are hereby revoked.

(2) With effect from the 30 October 2010, the Medical Preparations (Labelling and Package Leaflets) Regulations 1993 (S.I. No. 71 of 1993) (as amended) shall be revoked

PART 6

AMENDMENT OF EUROPEAN COMMUNITIES (CLINICAL TRIALS ON MEDICINAL PRODUCTS FOR HUMAN USE) REGULATIONS 2004

27. Regulation 4(1) of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (S.I. No. 190 of 2004) is hereby amended by—

- (a) the insertion of the following after the definition of “Commission Directive 2003/94/EC”—

“ ‘Community marketing authorisation’ has the meaning assigned to it by Regulation 3(1) of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007);” and

- (b) the substitution of the following for the definition of “marketing authorisation”—

“ ‘marketing authorisation’ has the meaning assigned to it by Regulation 3(1) of the Medicinal Products (Control of Placing on the

Market) Regulations 2007 and includes a Community marketing authorisation;”.

Collective citation for Medicinal Products (Prescription and Control of Supply) Regulations, 2003 (as amended)

28. The Medicinal Products (Prescription and Control of Supply) Regulations 2003 and 2005, the Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007 (S.I. No. 201 of 2007) and Part 4 of these Regulations shall be construed as one and may be cited together as the Medicinal Products (Prescription and Control of Supply) Regulations, 2003 to 2007.

Collective citation for European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (as amended)

29. The European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 to 2006, Regulation 16(2) of the Medicinal Products (Control of Manufacture) Regulations 2007 (S.I. No. 539 of 2007) and Regulation 27 of these Regulations shall be construed as one and may be cited as the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 to 2007.

SCHEDULE 1

EXEMPTIONS FROM THE AUTHORISATION AND CERTIFICATION
REQUIREMENTS OF REGULATION 5

1. The provisions of paragraphs (1) and (2) of Regulation 6 shall not apply to—
 - (a) any medicinal product intended for research and development trials, but without prejudice to the provisions of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (S.I. No. 190 of 2004) (as amended);
 - (b) to the sale or supply of a medicinal product in accordance with any exception or exemption set out in the 2001 Directive;
 - (c) the importation of a medicinal product, from a country that is not an EEA State, by a person for his own personal use, not being an importation resulting directly from a mail order advertisement directed at members of the public.

2. The provisions of paragraphs (1) and (2) of Regulation 6 shall not apply to the sale or supply of a medicinal product in response to a bona fide unsolicited order, formulated in accordance with the specifications of a practitioner for use by his individual patients on his direct personal responsibility, in order to fulfil the special needs of those patients, but such sale or supply shall be subject to the conditions specified in paragraph 3.

3. The conditions referred to in paragraph 2 are that—
 - (a) the medicinal product is supplied to a practitioner or for use in a pharmacy under the supervision of a pharmacist, in accordance with paragraph 2;
 - (b) no advertisement or representation relating to the medicinal product is issued with a view to it being seen by the general public in the State and that no advertisement relating to the product, by means of any catalogue, price list or circular letter is issued by, at the request or with the consent of, the person selling the product by retail or by way of wholesale dealing or the person who manufactures it, and that the sale or supply is in response to a bona fide unsolicited order;
 - (c) the manufacture of the medicinal product is carried out under the supervision of such staff and such precautions are taken as are adequate to ensure that the product is of the character required by and meets the specifications of the practitioner who requires it;
 - (d) written records as to the manufacture in accordance with subparagraph (c) are made and maintained and are available to the Board on request;

- (e) if the medicinal product is manufactured in the State, or imported into the State from a third country, the product—
- (i) is manufactured or imported by the holder of a manufacturer's authorisation which relates specifically to the manufacture or import of the medicinal product to which paragraph 2 applies; or
 - (ii) has been manufactured or imported as an investigational medicinal product by the holder of a manufacturing authorisation granted by the Board in respect of such products under Regulation 37 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 or Regulation 8 of the Medicinal Products (Control of Manufacture) Regulations 2007; and
- (f) the medicinal product is distributed by way of wholesale dealing by the holder of a wholesaler's authorisation or by the person who has manufactured or imported the product, being the holder of a manufacturer's authorisation which relates specifically to the manufacture or importation of the medicinal product concerned.

4. (1) Subject to the following subparagraphs, the provisions of paragraphs (1) and (2) of Regulation 6 shall not apply to anything done—

- (a) by a practitioner which relates to a medicinal product specially prepared by him, or to his order, for administration to one or more of his patients, and consists of procuring the manufacture of a stock of the product with a view to administering it to such patients; or
- (b) in a pharmacy and is done there by or under the supervision of a pharmacist, and consists of procuring the manufacture of a stock of medicinal products with a view to dispensing them in accordance with paragraph 2.

(2) The exemption conferred by subparagraph (1) shall not apply to procuring the manufacture of medicinal products unless those products are to be manufactured by the holder of an authorisation referred to in Article 40 of the 2001 Directive which relates specifically to the manufacture of the medicinal products to which paragraph 2 applies.

(3) The exemption conferred by subparagraph (1) shall not apply to anything done by a practitioner in relation to a stock held by him or her of such medicinal products in excess of 3 litres of fluid and 1 kilogram of solids of all medicinal products to which that subparagraph relates.

5. (1) The provisions of paragraphs (1) and (2) of Regulation 6 shall not apply to the placing on the market by way of supplying any medicinal product to which this paragraph applies if the conditions set out in subparagraph (3) are satisfied.

(2) The medicinal products to which this paragraph applies are medicinal products for use by being administered to one or more human beings and which may be lawfully sold or supplied otherwise than in accordance with a prescription given by a practitioner.

(3) The conditions referred to in subparagraph (1) are that—

- (a) the medicinal product is sold or supplied to a person exclusively for use by him or her in the course of a business carried on by him or her for the purposes of administering it or causing it to be administered to one or more human beings otherwise than by selling it;
- (b) if sold or supplied through the holder of a wholesaler's authorisation, the medicinal product is sold or supplied to such a person, and for such use by him, as is described in subparagraph (3)(a) above;
- (c) where the manufacture of the medicinal product is procured, it is procured by such a person, and for such use by him, as is described in subparagraph (3)(a) above;
- (d) the medicinal product is prepared by or under the supervision of a pharmacist;
- (e) if the medicinal product is manufactured in the State, or is imported into the State from a third country, the product is manufactured or imported by the holder of a manufacturer's authorisation which relates specifically to the manufacture or import of the medicinal product to which paragraph 2 applies; and
- (f) no advertisement or representation relating to the medicinal product is issued with a view to it being seen by the general public in the State and that no advertisement relating to the product, by means of any catalogue, price list or circular letter is issued by, at the request or with the consent of, the person selling that product by retail or by way of wholesale dealing or the person who manufactures it, and that the sale or supply is in response to a bona fide unsolicited order.

6. (1) The provisions of paragraphs (1) and (2) of Regulation 6 shall not apply to a medicinal product that is a radiopharmaceutical and which is prepared, at the time at which it is intended to be administered, by or under the responsibility of the person by whom it is to be administered, in accordance with the manufacturer's instructions, exclusively from a kit, generator or precursor (or from more than one of these) in respect of which a Community marketing authorisation or marketing authorisation is in force and in an establishment that is licensed by the Radiological Protection Institute of Ireland to use such medicinal products.

(2) In this paragraph—

'generator' means any system incorporating a fixed parent radionuclide from which is produced a daughter radionuclide which is to be removed by elution or by any other method and is to be used in a radiopharmaceutical;

‘kit’ means any product to be reconstituted or combined with radionuclides in a final radiopharmaceutical, usually prior to administration;

‘precursor’ means a radionuclide produced for the radio-labelling of another substance prior to its administration, other than a radionuclide which is incorporated in or produced from a generator or is included in a radiopharmaceutical;

‘radiopharmaceutical’ means any medicinal product which, when ready for use, contains one or more radionuclides intended for a medicinal purpose.

(3) Nothing in this paragraph shall permit the handling of a medicinal product which is a radiopharmaceutical, in contravention of the provisions of the Radiological Protection Act, 1991 (Ionising Radiation) Order 2000 (S.I. No. 125 of 2000) or the administration of any such product in contravention of the provisions of the European Communities (Medical Ionising Radiation Protection) Regulations 2002 (S.I. No. 478 of 2002).

7. A person who sells or supplies a medicinal product in accordance with any of paragraphs 2 to 6 shall maintain, and keep for a period of at least 5 years, a record showing—

- (a) the source from which that person obtained the product;
- (b) the person to whom and the date on which the sale or supply was made;
- (c) the quantity of each sale or supply;
- (d) the batch number of the batch of that product from which the sale or supply was made; and
- (e) details of any suspected adverse reaction to the product so sold or supplied of which he or she is aware.

8. A person required to maintain the records referred to in paragraph 7 shall—

- (a) notify the Board of any suspected adverse reaction such as is mentioned in subparagraph (e) thereof which is a serious adverse reaction; and
- (b) make available for inspection at all reasonable times by the Board the records referred to in that paragraph.

SCHEDULE 2

PROCEDURAL PROVISIONS RELATING TO PROPOSALS TO GRANT SUBJECT TO THE CARRYING OUT OF CERTAIN OBLIGATIONS, PROPOSALS TO GRANT OTHERWISE THAN IN ACCORDANCE WITH THE APPLICATION, PROPOSALS TO REFUSE TO GRANT OR VARY, PROPOSALS TO MAKE THE AUTHORISATION OR CERTIFICATE CONDITIONAL ON THE CARRYING OUT OF CERTAIN OBLIGATIONS, AND PROPOSALS TO SUSPEND, VARY OR REVOKE AN AUTHORISATION OR CERTIFICATE

1. In this Schedule—

‘authorisation’ means a marketing authorisation;

‘certificate’ means a certificate of registration or, as the case may be, a certificate of traditional-use registration; 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 or certificate,
- (b) to grant an authorisation or certificate subject to the carrying out of certain obligations,
- (c) to grant an authorisation or certificate other than in accordance with the application,
- (d) to revoke, vary or suspend an authorisation or certificate,
- (e) not to vary an authorisation or certificate on the holder’s application to vary, or
- (f) to make an authorisation or certificate conditional on the carrying out of certain obligations,

the Board shall notify the applicant or the holder of the authorisation or certificate 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 the holder of the authorisation or certificate 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 considering the representations, decide whether to grant the authorisation or certificate, revoke, vary or suspend an authorisation or certificate or confirm or alter its decision, as the case may be.

6. Paragraph 2 shall not apply to an urgent safety restriction imposed by the Board on the holder of an authorisation or certificate, in accordance with Regulation 13.

7. (1) Paragraph 2 shall not apply to the suspension of an authorisation or certificate where it appears to the Board that, in the interests of safety, it is necessary to suspend the authorisation or certificate 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 or certificate should be further suspended or revoked, the Board shall proceed in accordance with the provisions of paragraphs 2 to 5.



GIVEN under the 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 Directive 2001/83/EC (as amended by Directive 2004/27/EC) insofar as that Directive relates to the placing on the market and marketing of medicinal products for human use.

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