AN BILLE UM BORD LEIGHEASRA NA hÉIREANN (FORÁLACHA ILGHNÉITHEACHA) 2005
IRISH MEDICINES BOARD (MISCELLANEOUS PROVISIONS) BILL 2005

Mar a ritheadh ag Dáil Éireann
As passed by Dáil Éireann

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AN BILLE UM BORD LEIGHEASRA NA hÉIREANN (FORÁLACHA ILGHNÉITHEACHA) 2005

IRISH MEDICINES BOARD (MISCELLANEOUS PROVISIONS) BILL 2005

BILL

entitled

AN ACT TO AMEND THE MISUSE OF DRUGS ACT 1977 (AS AMENDED BY THE MISUSE OF DRUGS ACT 1984); TO AMEND THE IRISH MEDICINES BOARD ACT 1995; TO AMEND THE CONTROL OF CLINICAL TRIALS ACT 1987; TO AMEND THE HEALTH ACTS 1947 TO 2005; AND TO CONSEQUENTIALLY AMEND REGULATIONS THAT ARE EITHER MADE UNDER THE IRISH MEDICINES BOARD ACT 1995 OR REFERRED TO IN SECTION 34(4) OF THAT ACT AND TO AMEND THE ANIMAL REMEDIES ACT 1993.

BE IT ENACTED BY THE OIREACHTAS AS FOLLOWS:

PART 1

Preliminary

Short title, collective citation, construction and commencement.

1.—(1) This Act may be cited as the Irish Medicines Board (Miscellaneous Provisions) Act 2006.

(2) The Misuse of Drugs Acts 1977 and 1984 and *Part 2* may be cited together as the Misuse of Drugs Acts 1977 to 2006 and shall be construed together as one.

(3) The Irish Medicines Board Act 1995 and *Part 3* may be cited together as the Irish Medicines Board Acts 1995 and 2006 and shall be construed together as one.

(4) The Control of Clinical Trials Acts 1987 and 1990 and *Part 4* may be cited together as the Control of Clinical Trials Acts 1987 to 2006 and shall be construed together as one.

(5) The Health Acts 1947 to 2005 and *Part 5* may be cited together as the Health Acts 1947 to 2006 and shall be construed together as one.

(6) The Animal Remedies Act 1993 and *Part 7* may be cited together as the Animal Remedies Acts 1993 and 2006.

(7) This Act (other than *Part 7*) shall come into operation on such day or days as the Minister for Health and Children may appoint by order or orders either generally or with reference to any particular purpose or provision and different days may be so appointed for different purposes or provisions.

Interpretation.

2.—A reference in this Act to any enactment shall be construed as a reference to the enactment as amended, adapted or extended by or under any other enactment including this Act.

PART 2

Amendment of Misuse of Drugs Act 1977

Amendment of section 1 of Misuse of Drugs Act 1977 (interpretation).

3.—Section 1(1) of the Misuse of Drugs Act 1977 (as amended by section 2 of the Misuse of Drugs Act 1984) is amended—

(*a*) by inserting the following before the definition of "cannabis":

" 'business' includes a profession;",

(*b*) by inserting the following after the definition of "forged prescription":

" 'Irish Medicines Board' means the Irish Medicines Board established under section 3 of the Irish Medicines Board Act 1995;",

(*c*) in the definition of "practitioner", by substituting ", a registered veterinary surgeon and a registered nurse" for "and a registered veterinary surgeon", and

(*d*) by inserting the following after the definition of "registered medical practitioner":

" 'registered nurse' means a person whose name is entered in the register of nurses maintained by An Bord Altranais under section 27 of the Nurses Act 1985;".

Amendment of section 5 of Misuse of Drugs Act 1977 (regulations to prevent misuse of controlled drugs).

4.—Section 5 of the Misuse of Drugs Act 1977 is amended—

(*a*) in subsection (1), by substituting the following for paragraph (*f*):

"(*f*) subject to subsection (1A) of this section, regulating the issue by—

(i) registered medical practitioners, registered dentists or registered veterinary surgeons, or

(ii) registered nurses, or registered nurses belonging to a class of registered nurses,

of prescriptions for controlled drugs and the supply of controlled drugs on prescription,",

(*b*) by inserting the following after subsection (1):

"(1A) The Minister shall only exercise the power to make regulations under subsection (1)(*f*) of this section in the case of registered nurses, or registered nurses belonging to a class of registered nurses, if the Minister, after having had regard to the nature and purpose of the controlled drug concerned (including any deleterious effects which may arise from the misuse thereof), is satisfied that it is reasonably safe to permit the issue by registered nurses, or registered nurses belonging to a class of registered nurses, of prescriptions for that drug.",

(*c*) in subsection (2), in paragraph (*a*), by inserting "(other than a registered nurse)" after "practitioner", and

(*d*) by inserting the following after subsection (2):

"(3) Subject to section 13 of this Act, the Minister may exercise the Minister's power to make regulations under this section so as to secure that it is not unlawful under this Act for a practitioner who is a registered nurse, or a practitioner who is a registered nurse belonging to a class of registered nurses, for the purpose of the practitioner's profession as a registered nurse, to prescribe, administer, manufacture, compound or supply a controlled drug if the Minister, after having had regard to the nature and purpose of the controlled drug (including any deleterious effects which may arise from the misuse thereof), is satisfied that it is reasonably safe to permit the practitioner, for the purpose of the practitioner's profession as a registered nurse, to prescribe, administer, manufacture, compound or supply that controlled drug.".

Amendment of section 6 of Misuse of Drugs Act 1977 (directions prohibiting prescribing, supply, etc., of controlled drugs by practitioners or pharmacists, etc., convicted of offences).

5.—Section 6 of the Misuse of Drugs Act 1977 is amended—

(*a*) by inserting the following after subsection (1):

"(1A) Where a relevant person has after the commencement of this subsection been convicted of—

(*a*) an offence under this Act, or

(*b*) an offence against the Customs Acts in relation to the importation or exportation of a controlled drug,

the Minister may give a direction under subsection (2) of this section in respect of that person.",

(*b*) in subsection (2)(*b*), by substituting "or relevant person, be a direction prohibiting the pharmacist or relevant person, as the case may be, from having in the pharmacist's or relevant person's, as the case may be," for ", be a direction prohibiting him from having in his", and

(*c*) by inserting the following after subsection (6):

"(7) In this section, 'relevant person' means—

(*a*) a person, not being a pharmacist, keeping open shop for the dispensing or compounding of medical prescriptions in accordance with the provisions of the Pharmacy Acts 1875 to 1977, or

(*b*) any director, manager, secretary or other official of a person referred to in paragraph (*a*) of this definition which is a body corporate.".

Amendment of section 8 of Misuse of Drugs Act 1977 (investigation of cases where Minister considers there are grounds for special direction).

6.—Section 8(7) of the Misuse of Drugs Act 1977 (as amended by section 3 of the Misuse of Drugs Act 1984) is amended—

(*a*) in paragraph (*c*), by substituting "Council," for "Council.", and

(*b*) by inserting the following after paragraph (*c*):

"(*d*) in case the practitioner concerned is a registered nurse, to An Bord Altranais,".

Amendment of section 14 of Misuse of Drugs Act 1977 (licences etc.).

7.—Section 14 of the Misuse of Drugs Act 1977 is amended—

(*a*) in subsection (1), by substituting "Irish Medicines Board" for "Minister", and

(*b*) by inserting the following after subsection (2):

"(3) A licence, permit or authorisation—

(*a*) granted or issued by the Minister under subsection (1) (including granted or issued by way of being renewed) at any time before the commencement of this subsection, and

(*b*) in force immediately before that commencement,

shall, on and after that commencement but subject to the conditions, if any, attached under subsection (1) to it and in force immediately before that commencement, continue in force, unless sooner revoked under subsection (1), for the unexpired portion of the period of validity, if any, which it had left to run immediately before that commencement as if, on that commencement, the Irish Medicines Board had, under subsection (1)—

(*c*) granted or issued that licence, permit or authorisation, and

(*d*) attached to that licence, permit or authorisation those conditions, if any,

and the provisions of this Act shall apply to the licence, permit or authorisation accordingly.".

Amendment of section 17 of Misuse of Drugs Act 1977 (prohibition of cultivation of opium poppy or cannabis plant).

8.—Section 17 of the Misuse of Drugs Act 1977 (as amended by section 11(1) of the Misuse of Drugs Act 1984) is amended—

(*a*) in subsection (1)—

(i) by inserting "for the production of opium" after "poppy", and

(ii) by substituting "under section 14(1)" for "by the Minister",

and

(*b*) in subsection (2), by inserting "for the production of opium" after "poppy".

Amendment of section 24 of the Misuse of Drugs Act 1977 (powers to inspect and demand production of drugs, books or documents).

9.—Section 24 of the Misuse of Drugs Act 1977 is amended—

(*a*) in subsection (1)—

(i) by substituting "writing in that behalf by the Minister or the Irish Medicines Board" for "that behalf by the Minister in writing",

(ii) in paragraph (*a*), by adding "or as a practitioner" after "drugs", and

(iii) in paragraph (*c*), by inserting "(including any data within the meaning of the Data Protection Acts 1988 and 2003)" after "documents",

and

(*b*) by substituting the following for subsection (2):

"(2) For the purposes of enforcing this Act and any statutory instruments made thereunder, and without prejudice to the generality of subsection (1) of this section, a person authorised in writing in that behalf by the Council of the Pharmaceutical Society of Ireland may at all reasonable times—

(*a*) enter any building or premises in which a person keeps open shop for the dispensing or compounding of medical prescriptions,

(*b*) require any such person, or any person employed in connection with keeping such open shop for the dispensing or compounding of medical prescriptions, to produce any controlled drugs which are in his possession or under his control,

(*c*) require any such person, or any person so employed, to produce any books, records or other documents (including any data within the meaning of the Data Protection Acts 1988 and 2003) which relate to transactions concerning controlled drugs and which are in his possession or under his control, and

(*d*) inspect any controlled drug, book, record or other document produced in pursuance of a requirement under this section.

(3) Where the Minister or the Irish Medicines Board authorises a person under subsection (1) of this section, then the Minister or the Irish Medicines Board, as the case may be, shall furnish the person with a warrant of his authorisation.

(4) Where the Pharmaceutical Society of Ireland authorises a person under subsection (2) of this section, then it shall furnish the person with a warrant of his authorisation.

(5) Where—

(*a*) a person has been authorised by the Minister under subsection (1) of this section at any time before the commencement of this subsection,

(*b*) the authorisation is still in force immediately before that commencement, and

(*c*) either—

(i) the person has, before that commencement, been issued with a certificate of his authorisation, or

(ii) the person has not, before that commencement, been issued with a certificate of his authorisation,

then the Minister shall—

(*d*) in a case falling within paragraph (*c*)(i) of this subsection, furnish the person with a warrant of his authorisation upon the surrender of his certificate of authorisation,

(*e*) in a case falling within paragraph (*c*)(ii) of this subsection, as soon as reasonably practicable after that commencement, furnish the person with a warrant of his authorisation.

(6) Where a person authorised under subsection (1) or (2) of this section—

(*a*) claims to exercise a power by virtue of that authorisation, and

(*b*) is required by a person in relation to whom the power is proposed to be exercised, to produce evidence of that authorisation,

then the person so authorised shall not exercise that power until he has produced the warrant of authorisation furnished under this section to the person in relation to whom the power is proposed to be exercised.

(7) A certificate of authorisation referred to in subsection (5)(*c*)(i) of this section which has not been surrendered as referred to in subsection (5)(*d*) of this section

shall be deemed to be a warrant of authorisation furnished under this section to the person to whom the certificate of authorisation was furnished, and subsection (6) of this section shall be construed accordingly.".

PART 3

Amendment of Irish Medicines Board Act 1995

Amendment of section 1 of Irish Medicines Board Act 1995 (interpretation).

10.—Section 1(1) of the Irish Medicines Board Act 1995 is amended—

(*a*) by inserting the following before the definition of "the Board":

" 'administer', in relation to a medicinal product (and whether or not the product has been dissolved or dispersed in, or diluted or mixed with, any other substance), means to administer the product to a natural person—

(*a*) orally,

(*b*) by injection or other introduction into the body of the person, or

(*c*) by external application,

and whether or not by direct contact with the body of the person;";

(*b*) by inserting the following after the definition of "cosmetic product":

" 'drug precursor' means a scheduled substance as defined in Article 2 of Council Regulation (EC) No. 111/2005 of 22 December 2004[1];";

(*c*) by substituting the following for the definition of "medicinal product":

" 'medical device' means a medical device which falls within any of the definitions of 'medical device' in—

(*a*) Article 1 of Council Directive 90/385/EEC of 20 June 1990[2],

(*b*) Article 1 of Council Directive 93/42/EEC of 14 June 1993[3], or

(*c*) Article 1 of Directive 98/79/EC of 27 October 1998[4];

'medicinal product' has the meaning assigned to it by Directive 2001/83/EC of 6 November 2001[5], as amended from time to time;";

[1]OJ L22, 26.01.2005, p.1
[2]OJ L189, 20.07.1990, p.17
[3]OJ L169, 12.07.1993, p.1
[4]OJ L331, 07.12.1998, p.1
[5]OJ L311, 28.11.2001, p.67

(*d*) by inserting the following after the definition of "the Minister":

" 'premises' includes any aircraft, hovercraft, ship, stall or vehicle;";

(*e*) in the definition of "recognised trade unions and staff associations", by substituting "Board;" for "Board."; and

(*f*) by adding the following after the definition of "recognised trade unions and staff associations":

" 'registered dentist' means a person registered in the register established under the Dentists Act 1985;

'registered medical practitioner' means a person registered in the General Register of Medical Practitioners established under the Medical Practitioners Act 1978;

'registered nurse' means a person whose name is entered in the register of nurses maintained under section 27 of the Nurses Act 1985;

'veterinary medicinal product' has the meaning assigned to it by Directive 2001/82/EC of 6 November 2001[6], as amended from time to time.".

Amendment of section 4 of Irish Medicines Board Act 1995 (functions of Board).

11.—Section 4 of the Irish Medicines Board Act 1995 is amended—

(*a*) in subsection (1)—

(i) by substituting "Subject to subsection (4), the" for "The";

(ii) by substituting the following for paragraphs (*b*), (*c*) and (*d*):

"(*b*) to exercise the powers conferred on the competent authority by Directive No. 2001/83/EC of 6 November 20015,

(*c*) to exercise the powers conferred on the supervisory authority by Regulation (EC) No. 726/2004 of 31 March 2004[7],

(*d*) to exercise the powers conferred on the competent authority by Directive No. 2001/82/EC of 6 November 20016,";

(iii) by substituting the following for paragraph (*k*):

"(*k*) to establish and administer a service—

(i) for the receipt of applications from persons proposing to export any description of medicinal products, cosmetic products, veterinary medicinal products or medical devices, and

[6]OJ L311, 28.11.2001, p.1
[7]OJ L136, 30.04.2004, p.1

(ii) for the issue to such persons of certificates containing any statement relating to such description of such products or devices as the Board considers appropriate after having regard to—

(I) the law (whether under any enactment or rule of law or otherwise) in the State which is for the time being applicable to such description of such products or devices, and

(II) the law (whether under any enactment or rule of law or otherwise) in the place to which such description of such products or devices is to be exported which is for the time being applicable to such description of such products or devices,";

(iv) in paragraph (*p*), by substituting "1994)," for "1994)."; and

(v) by inserting the following after paragraph (*p*):

"(*q*) to exercise, subject to subsection (5), the powers specified in section 14(1) of the Misuse of Drugs Act 1977 (as amended by *section 7* of the *Irish Medicines Board (Miscellaneous Provisions) Act 2006*),

(*r*) the authorisation of persons under section 24 of the Misuse of Drugs Act 1977 (as amended by *section 9* of the *Irish Medicines Board (Miscellaneous Provisions) Act 2006*),

(*s*) to exercise the powers conferred on the competent authority by Directive 2001/20/EC of 4 April 2001[8],

(*t*) to exercise the powers conferred on the competent authority by Council Directive 76/768/EEC of 27 July 1976[9], as amended, Commission Directive 95/17/EC of 19 June 1995[10] and the European Communities (Cosmetic Products) Regulations 2004 (S.I. No. 870 of 2004),

(*u*) to exercise the powers conferred on the competent authority by Directive 2004/23/EC of 31 March 2004[11],

(*v*) to perform such other functions as are conferred on the Board by this or any other enactment (including any statutory instrument made thereunder).";

[8]OJ L121, 01.05.2001, p.34
[9]OJ L262, 27.09.1976, p.169
[10]OJ L140, 23.06.1995, p.26
[11]OJ L102, 7. 04. 2004, p.48

and

(*b*) by substituting the following for subsections (4) and (5):

"(4) The Board shall exercise the powers conferred on it under a paragraph of subsection (1) as the competent authority or the supervisory authority in accordance with any regulations made by the Minister, or the Minister for Agriculture and Food, for the purposes of giving effect to a Council Directive, Directive, Council Regulation or Commission Directive referred to in the paragraph.

(5) The Board shall, in exercising the powers referred to in subsection (1)(*q*), comply with any directive or guideline issued by the Minister to the Board in respect of policy in relation to controlled drugs.".

Amendment of section 5 of Irish Medicines Board Act 1995 (conferral of additional functions on Board).

12.—Section 5(1)(*a*) of the Irish Medicines Board Act 1995 is amended by inserting ", veterinary medicinal products, cosmetic products, drug precursors or medical devices" after "products".

Amendment of section 7 of Irish Medicines Board Act 1995 (members of Board).

13.—Section 7 of the Irish Medicines Board Act 1995 is amended by substituting the following for subsection (9):

"(9) Of the members of the Board—

(*a*) one shall be the chairperson of the Advisory Committee for Human Medicines,

(*b*) one shall be the chairperson of the Advisory Committee for Veterinary Medicines, and

(*c*) one shall be the chairperson of the Advisory Committee for Medical Devices,

but no member shall be the chairperson of more than one of those committees.".

Amendment of section 9 of Irish Medicines Board Act 1995 (Advisory Committees).

14.—Section 9 of the Irish Medicines Board Act 1995 is amended—

(*a*) by substituting the following for subsections (8) and (9):

"(8) The Board shall not refuse to grant a licence or authorisation in respect of—

(*a*) a medicinal product or class of medicinal products, or

(*b*) the manufacture or wholesale of a medicinal product or class of medicinal products,

on any ground relating to the safety, quality or efficacy of the medicinal product or class of medicinal products, as the case may be, unless the Board has requested the advice of the appropriate committee in relation thereto and considered the advice given pursuant to the request.

(9) Whenever the Board grants, suspends, renews or revokes a licence or other authorisation in respect of a medicinal product, it shall notify the appropriate committee of such grant, suspension, renewal or revocation.",

and

(*b*) by inserting the following after subsection (9):

"(10) In subsections (8) and (9), any reference to a medicinal product includes a reference to a medicinal product for animal use.".

Amendment of section 13 of Irish Medicines Board Act 1995 (fees).

15.—Section 13 of the Irish Medicines Board Act 1995 is amended—

(*a*) by substituting the following for subsection (1):

"(1) The Minister may make regulations providing for—

(*a*) the payment to and recovery by the Board of fees in relation to any matter arising in connection with the performance of any of its functions under section 4,

(*b*) different fees, exemption from the payment of fees, the payment of fees by instalments and the waiver, remission or refund (in whole or in part) of fees—

(i) in relation to any such matter, and

(ii) in different circumstances or classes of circumstances or for different cases or classes of cases,

(*c*) without prejudice to the generality of paragraph (*a*), the payment to and recovery by the Board of fees in relation to any application under regulations made under section 32 for—

(i) a licence, authorisation or certificate, or

(ii) the amendment or renewal of any such licence, authorisation or certificate,

(*d*) without prejudice to the generality of paragraphs (*a*) and (*c*), the payment to and recovery by the Board of annual fees in relation to any such licence, authorisation or certificate which is not annually renewable, and

(*e*) without prejudice to the generality of paragraph (*b*), different fees, exemption from the payment of fees, the payment of fees by instalments and the waiver, remission or refund (in whole or in part) of fees—

(i) in relation to any such licence, authorisation or certificate or any such amendment or renewal, and

(ii) in different circumstances or classes of circumstances or for different cases or classes of cases.";

(*b*) in subsection (2), by substituting "matter or application, the matter or application" for "application or matter, the application or matter"; and

(*c*) by inserting the following after subsection (4):

"(5) Without prejudice to the generality of regulations which may be made under this section for the recovery by the Board of fees payable under the regulations, the Board may recover, as a simple contract debt in any court of competent jurisdiction, from the person by whom it is payable any fee or part thereof due and payable under the regulations.

(6) Any regulations made under this section and in force immediately before the commencement of *section 15* of the *Irish Medicines Board (Miscellaneous Provisions) Act 2006* shall, on and after that commencement—

(*a*) continue in force and be deemed to be made under this section as amended by that section, and

(*b*) be liable to amendment and revocation under this section accordingly.".

Amendment of section 32 of Irish Medicines Board Act 1995 (regulations).

16.—Section 32 of the Irish Medicines Board Act 1995 is amended—

(*a*) in subsection (2)—

(i) by substituting ", cosmetic products or medical devices" for "or cosmetic products",

(ii) in paragraph (*a*)—

(I) by inserting "administration," after "supply,", and

(II) by inserting ", or the device or devices," after "the product or products",

(iii) in paragraph (*b*)—

(I) by inserting ", or the device or devices," after "the product or products", and

(II) by inserting "or such device or devices" after "such product or products",

(iv) in paragraph (*c*)—

(I) by inserting ", or the device or devices," after "the product or products",

(II) by substituting ", authorisation or certificate for such product or products or such device or

devices" for "for the advertisement of such products", and

(III) by substituting "or products or such device or devices which is or are" for "which is",

(v) in paragraph (*d*)—

(I) by inserting ", or the device or devices," after "the product or products",

(II) by inserting ", or such device or devices," after "such product or products" where it twice appears,

(vi) in paragraphs (*e*), (*f*) and (*g*), by inserting ", authorisations or certificates" after "licences",

(vii) in paragraph (*h*)—

(I) by inserting ", authorisation or certificates" after "of licences",

(II) by inserting ", or the device or devices," after "products",

(III) by inserting ", authorisations or certificates" after "or licences",

(viii) by substituting the following for paragraphs (*i*), (*j*), (*k*), (*l*) and (*m*):

"(*i*) the issuing of notices by authorised officers, within the meaning of section 32A, to the owners, occupiers or operators of premises requiring such owners, occupiers or operators to cease an activity—

(i) relating to the product or products, or the device or devices, to which the regulations relate, and

(ii) which, in the opinion of the authorised officer concerned, may pose a risk to human or animal health,

(*j*) subject to subsection (9), the specification that a reference to the supply of a medicinal product in—

(i) any regulations made under this section (whether made before, on or after the commencement of subsection (7)), or

(ii) any regulations referred to in section 34(4),

includes the administration of the product,

(*k*) subject to subsection (10), the prohibition of the administration of a medicinal product, or a class of medicinal products, specified in the regulations except by a member of a relevant profession in his or her capacity as such member, or—

(i) by a person, or a class of persons, specified in the regulations (which may be, or include, a person, or a class of persons, concerned in the provision of a health service, whether the health service is provided in a hospital, nursing home or clinic or otherwise), and

(ii) in accordance with the conditions, if any, specified in the regulations in relation thereto,

(*l*) subject to subsection (11) and without prejudice to the generality of any regulations made under paragraph (*k*), the prohibition of the sale or other supply of a medicinal product, or class of medicinal products, specified in the regulations except—

(i) pursuant to a prescription issued by a member of a relevant profession in his or her capacity as such member,

(ii) pursuant to a prescription issued by a registered nurse—

(I) who—

(A) is specified in the regulations as being a registered nurse who may, or

(B) belongs to a class of registered nurses specified in the regulations as being a class of registered nurses any member of which may,

issue a prescription in relation to the medicinal product, or class of medicinal products, as the case may be, concerned, and

(II) in accordance with such conditions, if any, as are specified in the regulations in relation thereto,

or

(iii) by such person, in or for such emergency circumstances and in accordance with such conditions, if any, as

are specified in the regulations in relation thereto,

(*m*) the regulation and control of medicinal products that are subject to classification under Article 70 of Directive 2001/83/EC of 6 November 2001[12] and, in particular, in the case of such a medicinal product the classification of which is a medicinal product not subject to medical prescription, the prohibition of the sale or other supply of the medicinal product except—

(i) by a person lawfully keeping open shop for the dispensing or compounding of medical prescriptions in accordance with the Pharmacy Acts 1875 to 1977 and in accordance with such conditions, if any, as are specified in the regulations in relation thereto, or

(ii) subject to subsection (12), by a person other than a person referred to in subparagraph (i) and in accordance with such conditions, if any, as are specified in the regulations in relation thereto,

(*n*) without prejudice to the generality of section 3(1) of the European Communities Act 1972, giving effect to acts of the institutions of the European Communities relating to medicinal products for human use, cosmetic products or medical devices,

(*o*) such incidental, supplementary and consequential provisions as appear to the Minister to be necessary or expedient for the purposes of the regulations.",

(*b*) by substituting the following for subsections (3) and (4):

"(3) Without prejudice to the generality of subsection (2)(*o*), regulations under subsection (2)(*n*) may contain such incidental, supplementary and consequential provisions as appear to the Minister to be necessary for the purposes of the regulations (including provisions repealing, amending or applying, with or without modification, other law, exclusive of this Act).

(4) A person who contravenes a regulation under this section shall be guilty of an offence and shall be liable—

(*a*) on summary conviction, to a fine not exceeding €2,000 or imprisonment for a term not exceeding one year or both,

(*b*) on conviction on indictment—

[12] OJ L311, 28. 11. 2001, p.67

(i) in the case of a first offence, to a fine not exceeding €120,000 or imprisonment for a term not exceeding 10 years or both,

(ii) in the case of any subsequent offence, to a fine not exceeding €300,000 or imprisonment for a term not exceeding 10 years or both.",

(*c*) by inserting the following after subsection (6):

"(7) Any reference (howsoever expressed) to the supply of a medicinal product in—

(*a*) any regulations made under this section (whether made before, on or after the commencement of this subsection), or

(*b*) any regulations referred to in section 34(4),

shall not include the administration of the product unless it is otherwise specified pursuant to subsection (2)(*j*).

(8) Subject to subsection (13), regulations made under this section may specify that a reference (howsoever expressed) to the sale or supply of a medicinal product or medical device in—

(*a*) the regulations, or

(*b*) other regulations made under this section (including made before the commencement of this subsection), or referred to in section 34(4), which the first-mentioned regulations amend,

include the giving of the product or device, as the case may be, whether with or without payment, in the course of the provision of a health service (whether the health service is provided in a hospital, nursing home or clinic or otherwise).

(9) The Minister shall only make regulations under this section to provide for a specification referred to in subsection (2)(*j*) if the Minister, after having had regard to the nature and purpose of the medicinal product concerned (including any deleterious effects which may arise from the misuse thereof), is satisfied that the specification is in the best interests of the persons to whom the product is usually administered.

(10) The Minister shall only make regulations under this section to provide for a prohibition and exception to the prohibition referred to in subsection (2)(*k*) if the Minister, after having had regard to the nature and purpose of the medicinal product, or class of medicinal products, concerned (including any deleterious effects which may arise from the misuse thereof), is satisfied that the prohibition and exception to the prohibition is in the best interests of the persons to whom the medicinal product, or class of medicinal products, as the case may be, is usually administered.

(11) The Minister shall only make regulations under this section to provide for a prohibition and exception to the prohibition referred to in subsection (2)(*l*) if the Minister, after having had regard to the nature and purpose of the medicinal product, or class of medicinal products, concerned (including any deleterious effects which may arise from the misuse thereof), is satisfied that the prohibition and exception to the prohibition is in the best interests of the persons to whom the medicinal product, or class of medicinal products, as the case may be, is usually administered.

(12) The Minister shall only make regulations under this section to provide for the exception referred to in subsection (2)(*m*)(ii) if the Minister, after having had regard to the nature and purpose of the medicinal product concerned (including any deleterious effects which may arise from the misuse thereof), is satisfied that it is reasonably safe to permit the medicinal product to be sold or otherwise supplied by a person other than a person referred to in subsection (2)(*m*)(i).

(13) The Minister shall only make regulations under this section to provide for a specification referred to in subsection (8) if the Minister, after having had regard to the nature and purpose of the medicinal product or medical device concerned (including any deleterious effects which may arise from the misuse thereof), is satisfied that the specification is in the best interests of the persons to whom the product or device, as the case may be, is usually given in the course of the provision of a health service.

(14) In this section, 'relevant profession' means—

(*a*) for the purposes of subsection (2)(*k*), any profession a member of which may, before the commencement of this subsection, and in his or her capacity as such member, have lawfully administered a medicinal product,

(*b*) for the purposes of subsection (2)(*l*), any profession a member of which may, before the commencement of this subsection, and in his or her capacity as such member, have lawfully issued a prescription for a medicinal product.".

Insertion of new sections 32A to 32F into Irish Medicines Board Act 1995 (authorised officers, etc.).

17.—The Irish Medicines Board Act 1995 is amended by inserting the following after section 32:

"Interpretation of sections 32A to 32F inclusive.

32A.—In this section and sections 32B to 32F inclusive—

'authorised officer' means—

(*a*) a person appointed under section 32B(1) to be an authorised officer, or

(*b*) an officer of customs and excise;

'inspect' includes search;

'premises' means any place, ship or other vessel, aircraft, railway wagon or other vehicle, and

includes a container used to transport relevant things;

'record' includes, in addition to a record in writing—

(*a*) a disc, tape, sound-track or other device in which information, sounds or signals are embodied so as to be capable (with or without the aid of some other instrument) of being reproduced in legible or audible form,

(*b*) a film, tape or other device in which visual images are embodied so as to be capable (with or without the aid of some other instrument) of being reproduced in visual form, and

(*c*) a photograph,

and any reference to a copy of a record includes—

(*d*) in the case of a record to which paragraph (*a*) applies, a transcript of the sounds or signals embodied therein,

(*e*) in the case of a record to which paragraph (*b*) applies, a still reproduction of the images embodied therein, and

(*f*) in the case of a record to which paragraphs (*a*) and (*b*) apply, such a transcript together with such a still reproduction;

'relevant person' means—

(*a*) the Minister,

(*b*) the Chief Executive,

(*c*) the Chief Executive Officer of the Health Service Executive, or

(*d*) the Council of the Pharmaceutical Society of Ireland;

'relevant thing' means—

(*a*) any medicinal product, cosmetic product or medical device, and

(*b*) any article or substance used in the manufacture, processing or storage of any medicinal product, cosmetic product or medical device;

'this Act' includes any regulations—

(*a*) made under this Act, or

(*b*) referred to in section 34(4).

Authorised officers.

32B.—(1) A relevant person—

(*a*) may appoint such and so many persons as the relevant person thinks fit to be authorised officers for the purposes of this Act, and

(*b*) shall furnish each authorised officer appointed by the relevant person with a warrant of the authorised officer's appointment.

(2) An authorised officer (other than an authorised officer who is an officer of customs and excise) shall, when performing a function imposed under this Act on an authorised officer, produce his or her warrant for inspection if requested to do so by a person affected by the performance of that function.

(3) For the purposes of this Act, an authorised officer may—

(*a*) subject to subsection (5), enter (if necessary by the use of reasonable force), at all reasonable times, any premises at which he or she has reasonable grounds for believing that—

(i) any trade, business or activity connected with the manufacture, processing, disposal, export, import, distribution, sale, supply, storage, packaging or labelling of any relevant thing is or has been carried on, or

(ii) books, records or other documents (including documents stored in non-legible form) relating to such trade, business or activity are kept,

(*b*) at such premises inspect and take copies of, any books, records, other documents (including documents stored in non-legible form) or extracts therefrom, which he or she finds in the course of his or her inspection,

(*c*) remove any such books, records or other documents from such premises and detain them for such period as he or she reasonably considers to be necessary for the purposes of his or her functions under this Act,

(*d*) carry out, or have carried out, such tests, examinations, analyses, inspections and checks of—

(i) the premises,

(ii) any relevant thing at the premises, or

(iii) any equipment, machinery or plant at the premises,

as he or she reasonably considers to be necessary for the purposes of his or her functions under this Act,

(*e*) require any person at the premises or the owner or person in charge of the premises and any person employed there to give to him or her such assistance and information and to produce to him or her such books, records or other documents (and in the case of documents or records stored in non-legible form, produce to him or her a legible reproduction thereof) that are in that person's power or procurement, as he or she may reasonably require for the purposes of his or her functions under this Act,

(*f*) without payment, take samples of any relevant thing found at the premises for the purposes of any test, examination or analysis,

(*g*) direct that such relevant thing found at the premises as he or she, upon reasonable grounds, believes contravenes a provision of this Act not be sold or distributed or moved from the premises, without his or her consent,

(*h*) secure for later inspection any premises or part of any premises in which a relevant thing is found or ordinarily kept, or books, records or other documents are found or ordinarily kept, for such period as may reasonably be necessary for the purposes of his or her functions under this Act,

(*i*) without payment, take possession of and remove from the premises for any test, examination or analysis any relevant thing found there, and detain it for such period as he or she considers reasonably necessary for the purposes of his or her functions under this Act,

(*j*) without payment, take samples of any relevant thing, detained pursuant to paragraph (*i*), for the purposes of any test, examination, or analysis,

(*k*) where the taking of samples of any relevant thing pursuant to paragraph (*f*)

or (*j*) is, for whatever reason, not practicable, without payment take the relevant thing concerned for the purposes of any test, examination or analysis,

(*l*) inspect and copy or extract information from any data within the meaning of the Data Protection Acts 1988 and 2003,

(*m*) require a person, having authority to do so, to break open any container or package, or to open any vending machine, or to permit him or her to do so, as he or she may reasonably require for the purposes of his or her functions under this Act, or

(*n*) require a person, who makes available facilities such as post office boxes, telecommunications or electronic mail address or other like facilities, to give him or her such assistance and information as he or she may reasonably require for the purposes of his or her functions under this Act in any case where the officer has reasonable grounds for believing that any relevant thing is being supplied by mail.

(4) When performing a function under this Act, an authorised officer may, subject to any warrant under subsection (6), be accompanied by such number of—

(*a*) other authorised officers,

(*b*) members of the Garda Síochána, or

(*c*) persons with expertise relating to any relevant thing,

as he or she considers appropriate in the circumstances of the case.

(5) An authorised officer shall not enter a dwelling, other than—

(*a*) with the consent of the occupier, or

(*b*) in accordance with a warrant issued under subsection (6).

(6) Upon the application of an authorised officer, a judge of the District Court, if satisfied that there are reasonable grounds for believing that—

(*a*) a relevant thing is to be found in any dwelling, or is being or has been subjected to any process or stored in any dwelling,

(*b*) a dwelling is occupied in whole or in part by an undertaking engaged in any trade, business or activity referred to in subsection (3)(*a*)(i), or

(*c*) books, records or other documents (including documents stored in non-legible form) referred to in subsection (3)(*a*)(ii) are being stored or kept in any dwelling,

may issue a warrant authorising a named authorised officer accompanied by such other authorised officers, members of the Garda Síochána, or persons with expertise relating to any relevant thing, as may be necessary, at any time or times, within one month of the date of issue of the warrant, to enter the dwelling and perform any of the functions of an authorised officer under subsection (3)(*b*) to (*n*).

(7) Any person who—

(*a*) obstructs or interferes with an authorised officer, a member of the Garda Síochána, or a person with expertise relating to any relevant thing, in the course of performing a function conferred on him or her by this Act or a warrant under subsection (6),

(*b*) impedes the performance by the officer, member, or person with expertise, as the case may be, of such function or fails or refuses to comply with a request or requirement of, or to answer a question asked by, the officer, member, or person with expertise, as the case may be, pursuant to this section, or

(*c*) in purported compliance with such request or requirement or in answer to such question gives information to the officer, member, or person with expertise, as the case may be, that he or she knows to be false or misleading in any material respect,

shall be guilty of an offence.

(8) Where an authorised officer, upon reasonable grounds, believes that a person has committed an offence under this Act, he or she may require that person to provide him or her with his or her name and the address at which he or she ordinarily resides.

(9) A statement or admission made by a person pursuant to a requirement under subsection (3)(*e*) shall not be admissible as evidence in proceedings brought against that person for an offence (other than an offence under subsection (7)).

(10) A person who falsely represents himself or herself to be an authorised officer shall be guilty of an offence.

(11) Nothing in this section shall be taken to compel the production by any person of a document which he or she would be exempt from production in proceedings in a court on the ground of legal professional privilege.

Taking of samples, etc. by authorised officers.

32C.—(1) Subject to subsection (3), where an authorised officer takes a sample of a relevant thing pursuant to section 32B(3)(*f*) or (*j*), he or she shall—

(*a*) divide the sample into 3 approximately equal parts,

(*b*) place each part into separate containers, and

(*c*) forthwith seal and mark each such container in such a manner as to identify it as part of the sample taken by that authorised officer.

(2) Where an authorised officer has complied with subsection (1), he or she shall—

(*a*) offer one of the sealed containers to the owner or person for the time being in charge or possession of the relevant thing from which the sample concerned was taken,

(*b*) retain one of the sealed containers, and

(*c*) forward, or cause to be forwarded, one of the sealed containers for test, examination or analysis of the sample concerned by a person mentioned in section 32D(1)(*a*), (*b*) or (*c*).

(3) Where a relevant thing is contained in a container and its division into parts pursuant to subsection (1) is, for whatever reason, not practicable, an authorised officer, who wishes to take samples of such relevant things for the purposes of any tests, examination or analysis shall take possession of 3 such containers belonging to the same batch, and each such container shall be deemed to be part of a sample for the purposes of subsection (1), and the provisions of subsections (1) and (2) shall apply thereto accordingly.

(4) Where an authorised officer takes a relevant thing pursuant to section 32B(3)(*k*), he or she shall—

(*a*) place the relevant thing in a container,

(*b*) forthwith seal and mark the container in such a manner as to identify it as a

relevant thing taken pursuant to that section, and

(*c*) forward, or cause to be forwarded, the sealed container for test, examination or analysis of the relevant thing by a person mentioned in section 32D(1)(*a*), (*b*) or (*c*).

Certificate of result of test, etc., of sample, etc.

32D.—(1) In any proceedings for an offence under this Act, a certificate in the form specified in Schedule 2 to this Act signed by—

(*a*) either—

(i) the State Chemist, or

(ii) another chemist employed or engaged at the State Laboratory and authorised by the State Chemist to sign the certificate,

(*b*) either—

(i) a public analyst appointed under section 10 of the Sale of Food and Drugs Act 1875, or

(ii) another analyst authorised by such a public analyst to sign the certificate, or

(*c*) a chemist or analyst appointed by the Board or the Council of the Pharmaceutical Society of Ireland,

stating the result of any test, examination or analysis of a sample of any relevant thing, or of a relevant thing, as the case may be, forwarded under section 32C(2)(*c*) or (4)(*c*) shall, with regard to that sample of the relevant thing, or the relevant thing, as the case may be, be evidence of the matters stated in the certificate unless the contrary is proved.

(2) In proceedings for an offence under this Act, a relevant thing, or a package containing a relevant thing, that purports to bear the name of the manufacturer or importer of that thing, or of the person who placed that thing on the market, shall, unless the contrary is proved, be evidence that the relevant thing was manufactured or imported, or placed on the market, as the case may be, by the person so named.

(3) In proceedings for an offence under this Act, a relevant thing, or a package containing a relevant thing, that bears a trademark shall, unless the contrary is proved, be evidence that the thing was manufactured by the person who at the time of the alleged commission of the offence owned that trademark.

(4) In this section, 'trademark' has the same meaning as it has in the Trade Marks Act 1996.

Penalties for offences.

32E.—(1) A person guilty of an offence under section 32B(7) or (10) shall be liable on summary conviction to a fine not exceeding €2,000, or to imprisonment for a term not exceeding 3 months, or to both.

(2) On conviction for an offence under this Act, the court may, in addition to any other penalty—

(*a*) order any relevant thing or any apparatus, equipment or other thing to which the offence relates, to be forfeited to a relevant person for destruction or other disposal as the relevant person thinks fit,

(*b*) upon application made to it by or on behalf of the relevant person, order the person convicted of the offence to pay to the relevant person all or part of the costs of such destruction or disposal subject to such conditions, if any, as are specified in the order.

Proceedings.

32F.—(1) Summary proceedings for an offence under this Act may be brought and prosecuted by a relevant person.

(2) Notwithstanding section 10(4) of the Petty Sessions (Ireland) Act 1851, summary proceedings for an offence under this Act may be instituted within 2 years from the date of the offence.

(3) References in section 382 of the Companies Act 1963 to a company shall, for the purposes of this Act, be construed as including references to a body corporate (whether or not a company within the meaning of that section) charged on indictment with an offence under this Act.".

Amendment of section 35 of Irish Medicines Board Act 1995 (amendment of enactments).

18.—Section 35(1) of the Irish Medicines Board Act 1995 is amended by substituting "SCHEDULE 1" for "the SCHEDULE".

Amendment of Schedule to Irish Medicines Board Act 1995.

19.—The Schedule to the Irish Medicines Board Act 1995 is amended by substituting "SCHEDULE 1" for "SCHEDULE".

Insertion of new Schedule 2 into Irish Medicines Board Act 1995.

20.—The Irish Medicines Board Act 1995 is amended by inserting the following after Schedule 1 to that Act (as amended by *section 19* of this Act):

"SCHEDULE 2

IRISH MEDICINES BOARD ACT 1995 (AS AMENDED BY THE IRISH MEDICINES BOARD (MISCELLANEOUS PROVISIONS) ACT 2006)

CERTIFICATE STATING RESULTS OF TEST, EXAMINATION OR ANALYSIS

This certificate is issued by me, the undersigned, for the purpose of section 32D of the Irish Medicines Board Act 1995 (as amended by *section 17* of the *Irish Medicines Board (Miscellaneous Provisions) Act 2006*), being—

[1]_____.

I hereby certify that I received, on the __ day of _____ ____, from [2]_____ of _____ a sample of the relevant thing/the relevant thing*, being [3]_____ for test, examination or analysis; which was undamaged, duly sealed and marked [4]_____.

I further certify that the said sample/relevant thing* has been tested, examined or analysed by me or under my direction and that the results are as follows—

[5]Signature_____

Date_____

Address_____

_____

_____

1. Here insert official title of person signing the certificate.

2. Here insert the name of the authorised officer who submitted the sample of the relevant thing, or the relevant thing, as the case may be.

3. Here insert the name or description of the relevant thing.

4. Here insert distinguishing mark on the sample of the relevant thing, or the relevant thing, as the case may be, and the date shown on its container as the date of sampling, or the date on which the relevant thing was taken into possession, as the case may be.

5. Here insert the relevant results as appropriate.

* Delete whichever is inapplicable.".

PART 4

Amendment of Control of Clinical Trials Act 1987

21.—Section 1(1) of the Control of Clinical Trials Act 1987 is amended— Amendment of section 1 of Control of Clinical Trials Act 1987 (interpretation).

(*a*) by inserting after the definition of "administered" the following:

" 'authorised officer' means an authorised officer appointed under section 15A(1);";

(*b*) by inserting the following after the definition of "ethics committee":

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

'medical device' means medical device within the meaning of section 1(1) of the Irish Medicines Board Act 1995;";

and

(*c*) by inserting the following after the definition of "participant":

" 'premises' includes any aircraft, hovercraft, ship, stall or vehicle;

'record' includes, in addition to a record in writing—

(*a*) a disc, tape, sound-track or other device in which information, sounds or signals are embodied so as to be capable (with or without the aid of some other instrument) of being reproduced in legible or audible form,

(*b*) a film, tape or other device in which visual images are embodied so as to be capable (with or without the aid of some other instrument) of being reproduced in visual form, and

(*c*) a photograph,

and any reference to a copy of a record includes—

(*d*) in the case of a record to which paragraph (*a*) of this definition applies, a transcript of the sounds or signals embodied therein,

(*e*) in the case of a record to which paragraph (*b*) of this definition applies, a still reproduction of the images embodied therein, and

(*f*) in the case of a record to which paragraphs (*a*) and (*b*) of this definition apply, such a transcript together with such a still reproduction;".

Amendment of section 2 of Control of Clinical Trials Act 1987 (restriction on application of Act, etc.).

22.—Section 2 of the Control of Clinical Trials Act 1987 is amended by inserting the following after subsection (3):

"(4) The provisions of this Act shall not apply in respect of any clinical trial that is subject to control under the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 (S.I. No. 190 of 2004).".

Amendment of section 13 of Control of Clinical Trials Act 1987 (offences).

23.—Section 13 of the Control of Clinical Trials Act 1987 is amended—

(*a*) in subsection (3), by substituting "2 years" for "12 months"; and

(*b*) by inserting the following after subsection (3):

"(4) An offence under this section may be prosecuted summarily by the Irish Medicines Board.".

Insertion of new section 15A into Control of Clinical Trials Act 1987 (authorised officers).

24.—The Control of Clinical Trials Act 1987 is amended by inserting the following after section 15:

"Authorised officers.

15A.—(1) The Irish Medicines Board may appoint any of its officers to be authorised officers for the purposes of this Act and any regulations under this Act.

(2) The Irish Medicines Board shall cause an authorised officer to be issued with a warrant identifying the officer as such an officer.

(3) An authorised officer shall, when performing a function or exercising a power in his capacity as an authorised officer, produce the warrant issued under subsection (2) to him or her if requested to do so by a person affected by the performance of the function or exercise of the power, as the case may be.

(4) Subject to subsections (5) and (6), an authorised officer may, for the purpose of ensuring that any provision of this Act or of any regulations under this Act is being complied with—

(*a*) at all reasonable times, enter and search a premises of any class or description,

(*b*) inspect any substance or product which is stored, or offered or kept for supply at such premises,

(*c*) require the production of, inspect and, if he thinks fit, take copies of any prescription, book, invoice, order, record, register, or other document or of any entry in any such book, invoice, order, record, register, or other document at such premises,

(*d*) inspect and copy or extract information from any data within the meaning of

the Data Protection Acts 1988 and 2003,

(*e*) take (without payment) samples of any medicinal product, medical device or substance stored, or offered or kept for supply at such premises for test, examination or analysis,

(*f*) seize and detain any medicinal product, medical device, substance or article,

(*g*) take any document which he has reasonable cause to believe to be a document which may be required as evidence in proceedings under this Act or any regulations under this Act.

(5) An authorised officer shall not other than with the consent of the occupier enter a private dwelling (other than any part of the private dwelling used by a registered medical practitioner or registered dentist for carrying on his or her professional practice) unless he or she has obtained a warrant from a judge of the District Court under subsection (8) authorising such entry.

(6) An authorised officer, for the purpose of exercising any of the powers conferred on him under subsection (4), may require any other person, having authority to do so, to break open any container or package, or to permit him to do so.

(7) Where an authorised officer seizes any medicinal product, medical device, substance, article or document in the exercise of a power conferred on him by subsection (4), he or she shall inform the person from whom it is seized of that fact.

(8) If a judge of the District Court is satisfied, on the sworn information of an authorised officer, that there are reasonable grounds to authorise entry into any of those premises set out at subsection (5), the judge may issue a warrant authorising such an authorised officer, accompanied, if appropriate, by other authorised officers or by a member or members of the Garda Síochána, or any combination thereof, at any time or times within one month from the date of issue of the warrant, on production of the warrant requested, to enter those premises or part thereof and to exercise any of the powers conferred on such an authorised officer under this Act or any regulations under this Act.

(9) A person shall not wilfully obstruct or interfere with the exercise of a power by an authorised officer pursuant to this Act or any regulations under this Act.

(10) A person shall not, without reasonable excuse, fail to comply with any request made by

an authorised officer under this Act or any regulations made under this Act.".

PART 5

Amendment of Health Acts 1947 to 2005

Amendment of section 54 of Health Act 1947 (regulations for prevention of danger from food and drink).

25.—Section 54 of the Health Act 1947 (as amended by the European Communities (Health Act 1947 Amendment of Sections 54 and 61) Regulations 1991 (S.I. No. 333 of 1991)) is repealed and the following substituted:

"Regulations for prevention of danger from food and drink.

54.—(1) The Minister may, after consultation with the Minister for Enterprise, Trade and Employment and the Minister for Agriculture and Food, make regulations providing for—

(*a*) the prevention of danger to the public health arising from the manufacture, preparation, importation, storage, distribution or exposure for sale of food intended for sale for human consumption,

(*b*) the prevention of contamination of food intended for sale for human consumption,

(*c*) the prohibition and prevention of the sale or offering or keeping for sale of—

(i) articles of food intended for human consumption,

(ii) living animals intended for such food,

(iii) materials or articles used or intended for use in the preparation or manufacture of such food,

which are diseased, contaminated or otherwise unfit for human consumption,

(*d*) the protection of consumer interests (including regulations requiring persons operating in the retail, restaurant or catering sectors to provide information on the country of origin of meat sold or otherwise supplied to consumers where, in the opinion of the Minister, such information is not already adequately provided under national or EU legislation),

(*e*) without prejudice to the generality of section 3(1) of the European Communities Act 1972, giving effect to acts of the institutions of the European

Communities relating to the official control of foodstuffs for the protection of health.

(2) Regulations made under this section may contain such incidental, supplementary and consequential provisions as appear to the Minister to be necessary for the purpose of the regulations (including, in the case of regulations made under subsection (1)(*e*), regulations repealing, amending or applying, with or without modifications, other law, exclusive of this Act).

(3) A person who has gained access to information by virtue of inspections made in the enforcement of regulations made under this section shall not disclose such information unless it is necessary to do so for the purpose of the enforcement of the regulations.

(4) A person who, on or after the commencement of this section, contravenes a regulation made under this section, or contravenes subsection (3), shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding €5,000 or to imprisonment for a term not exceeding 6 months or both.

(5) A person guilty of an offence under subsection (4) shall, on each day on which the contravention to which that offence relates is continued by the person after having been convicted of that offence, be guilty of an offence and shall be liable on summary conviction to a fine not exceeding €500 or to imprisonment for a term not exceeding one month or both.

(6) Regulations made under the repealed section and in force immediately before the commencement of this section shall be deemed to be made under this section and may be amended or revoked accordingly.

(7) In this section—

'persons operating in the retail, restaurant or catering sectors' includes food business operators within the meaning of Article 3 of the European Parliament and Council Regulation (EC) No. 178/2002 of 28 January 2002[13];

'protection of consumer interests' includes all measures for the prohibition or prevention of the processing, storage, transport, distribution, trading or selling to the prejudice of the consumer of any food which is not of the nature, substance or quality demanded by the consumer;

'repealed section' means section 54 of this Act as in force immediately before the commencement of this section.".

[13] OJ L31, 1.2.2002, p.1

Amendment of section 59 of Health Act 1970.

26.—Section 59(2) of the Health Act 1970 is amended by inserting, "or on the prescription of a registered nurse (being a person whose name is entered in the register of nurses maintained under section 27 of the Nurses Act 1985) entitled pursuant to any enactment to prescribe the drugs, medicines or medical or surgical appliances so obtained," after "practitioner".

Amendment of section 66 of Health Act 1970 (child health service).

27.—Section 66 of the Health Act 1970 is amended by substituting the following for subsections (2), (3) and (4):

"(2) The Health Service Executive shall make available without charge a health examination and treatment service for pupils who attend any primary school or who are taught at home.

(3) The Health Service Executive may, by notice given to a school manager, or governing body of a school, require the school manager or governing body, as the case may be, to provide reasonable facilities for an examination under this section.

(4) A school manager or governing body given a notice under subsection (3) shall comply with the notice.".

Amendment of section 67 of Health Act 1970 (dental, ophthalmic and aural services).

28.—Section 67 of the Health Act 1970 is amended—

(*a*) in subsection (1), by deleting "and persons with limited eligibility",

(*b*) in subsection (3), by substituting "Charges" for "Save as provided for under subsection (4), charges,", and

(*c*) by deleting subsection (4).

Amendment of section 1 of Health (Amendment) Act 1994 (free dental health services for children).

29.—Section 1(1) of the Health (Amendment) Act 1994 is amended by substituting "any primary school or who are taught at home, and who" for "national school or a school standing specified in an order under section 66(3) of the Health Act, 1970, and".

PART 6

Consequential Amendments to Regulations Made Under Section 32 of Irish Medicines Board Act 1995 or Referred to in Section 34(4) of that Act

Amendment of regulation 3 of Medical Preparations (Wholesale Licences) Regulations 1993.

30.—Regulation 3 of the Medical Preparations (Wholesale Licences) Regulations 1993 (S.I. No. 39 of 1993) (as amended by the Medicinal Products (Amendment) Regulations 2004 (S.I. No. 663 of 2004)) is amended by deleting the definition of "State Chemist".

Revocation of regulations 11, 12 and 13 of, and Schedule to, Medical Preparations (Wholesale Licences) Regulations 1993.

31.—The Medical Preparations (Wholesale Licences) Regulations 1993 (S.I. No. 39 of 1993) (as amended by the Medical Preparations (Wholesale Licences) (Amendment) Regulations 1996 (S.I. No. 41 of 1996) and the Medicinal Products (Amendment) Regulations 2004 (S.I. No. 663 of 2004)) are amended by revoking regulations 11, 12 and 13 and the Schedule.

32.—Regulation 3 of the Medical Preparations (Licensing of Manufacture) Regulations 1993 (S.I. No. 40 of 1993) (as amended by the Medicinal Products (Amendment) Regulations 2004 (S.I. No. 663 of 2004)) is amended by deleting the definition of "State Chemist".

Amendment of regulation 3 of Medical Preparations (Licensing of Manufacture) Regulations 1993.

33.—The Medical Preparations (Licensing of Manufacture) Regulations 1993 (S.I. No. 40 of 1993) (as amended by the Medical Preparations (Licensing of Manufacture) (Amendment) Regulations 1996 (S.I. No. 42 of 1996) and the Medicinal Products (Amendment) Regulations 2004 (S.I. No. 663 of 2004)) are amended by revoking regulations 11, 12 and 13 and Schedule III.

Revocation of regulations 11, 12 and 13 of, and Schedule III to, Medical Preparations (Licensing of Manufacture) Regulations 1993.

34.—The Medical Preparations (Labelling and Package Leaflets) Regulations 1993 (S.I. No. 71 of 1993) (as amended by the Medical Preparations (Labelling and Package Leaflets) (Amendment) Regulations 1999 (S.I. No. 187 of 1999)) are amended by revoking regulation 13.

Revocation of regulation 13 of Medical Preparations (Labelling and Package Leaflets) Regulations 1993.

35.—Regulation 2 of the Medicinal Products (Licensing and Sale) Regulations 1998 (S.I. No. 142 of 1998) (as amended by the Medicinal Products (Amendment) Regulations 2004 (S.I. No. 663 of 2004)) is amended by deleting the definition of "State Chemist".

Amendment of regulation 2 of Medicinal Products (Licensing and Sale) Regulations 1998.

36.—The Medicinal Products (Licensing and Sale) Regulations 1998 (S.I. No. 142 of 1998) (as amended by the Medicinal Products (Amendment) Regulations 2004 (S.I. No. 663 of 2004)) are amended by revoking regulations 12, 13 and 13A and the Second Schedule.

Revocation of regulations 12, 13 and 13A of, and Second Schedule to, Medicinal Products (Licensing and Sale) Regulations 1998.

37.—Regulation 4(1) of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) is amended by deleting the definition of "authorised officer".

Amendment of regulation 4(1) of Medicinal Products (Prescription and Control of Supply) Regulations 2003 (interpretation).

38.—The Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) are amended by revoking regulations 21 and 22 and the Sixth Schedule.

Revocation of regulations 21 and 22 of, and Sixth Schedule to, Medicinal Products (Prescription and Control of Supply) Regulations 2003.

39.—Regulation 23 of the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) is amended by substituting "section 32B of the Act" for "regulation 21 herein".

Amendment of regulation 23 of Medicinal Products (Prescription and Control of Supply) Regulations 2003.

Revocation of regulation 18 of Medical Preparations (Advertising) Regulations 1993.

40.—The Medical Preparations (Advertising) Regulations 1993 (S.I. No. 76 of 1993) are amended by revoking regulation 18.

PART 7

Amendment of Animal Remedies Act 1993

Regulations and fees and increase of fines.

41.—(1) The Animal Remedies Act 1993 is amended—

(*a*) in section 8(1)—

(i) in paragraph (*a*)(iii), by inserting "and any building or structure containing such" after "animal remedies", and

(ii) in paragraph (*b*)(iii)(I) and (II), by inserting "or certificates" after "authorisations",

(*b*) in section 23—

(i) in subsection (1)—

(I) in paragraph (*a*), by substituting "€5,000" for "£1,000", and

(II) in paragraph (*b*), by substituting—

(A) in subparagraph (i), "€150,000" for "£100,000", and

(B) in subparagraph (ii), "€350,000" for "£250,000",

and

(ii) in subsection (2)—

(I) in paragraph (*a*), by substituting "€5,000" for "£1,000", and

(II) in paragraph (*b*), by substituting—

(A) in subparagraph (i), "€50,000" for "£25,000", and

(B) in subparagraph (ii), "€100,000" for "£50,000",

and

(*c*) in section 29—

(i) by substituting for subsection (1) the following:

"(1) There shall be paid—

(*a*) on an application for the grant of a licence the issue of an authorisation or a certificate or the provision of a service under regulations made under section 8 or a

renewal or amendment of any of them, such fee (if any),

(*b*) in respect of a licence, authorisation or certificate under regulations made under section 8 which is in force for a definite or indefinite period of more than 12 months, such annual fee (if any), and

(*c*) in respect of any fee or levy to which regulations made under section 8(2)(*b*)(vii) relate, such fee or levy.",

(ii) in subsection (2), by substituting "licences, authorisations, certificates or services" for "licences or authorisations", and

(iii) in subsection (3)(*b*)(i), by substituting "authorisations or certificates" for "authorisations".

(2) *Subsection (1)(b)* does not have effect as respects offences committed before the passing of this Act.