Number 29 *of* 1995

IRISH MEDICINES BOARD ACT 1995

REVISED

Updated to 30 June 2026

This Revised Act is an administrative consolidation of the *Irish Medicines Board Act 1995*. It is prepared by the Law Reform Commission in accordance with its function under the *Law Reform Commission Act 1975* (3/1975) to keep the law under review and to undertake revision and consolidation of statute law.

All Acts up to and including the *Critical Infrastructure Act 2026* (16/2026), enacted 25 June 2026, and all statutory instruments up to and including the *Statistics (Structural Business Inquiry) (Amendment) Order 2026* (S.I. No. 311 of 2026), made 30 June 2026, were considered in the preparation of this Revised Act.

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Number 29 *of* 1995

IRISH MEDICINES BOARD ACT 1995

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SCHEDULE

AMENDMENT OF ENACTMENTS

Number 29 *of* 1995

IRISH MEDICINES BOARD ACT 1995

REVISED

Updated to 30 June 2026

AN ACT TO MAKE FURTHER PROVISION IN RELATION TO THE REGULATION OF THE MANUFACTURE, PRODUCTION, PREPARATION, IMPORTATION, ADVERTISEMENT, SALE AND DISTRIBUTION OF MEDICINAL AND COSMETIC PRODUCTS, FOR THOSE AND OTHER PURPOSES TO PROVIDE FOR THE ESTABLISHMENT OF A BOARD TO BE KNOWN AS THE IRISH MEDICINES BOARD, TO PROVIDE FOR THE DISSOLUTION OF THE NATIONAL DRUGS ADVISORY BOARD AND THE CONFERRAL OF ITS FUNCTIONS ON THE IRISH MEDICINES BOARD AND TO PROVIDE FOR RELATED MATTERS. [15*th November*, 1995]

BE IT ENACTED BY THE OIREACHTAS AS FOLLOWS:

Annotations

Modifications (not altering text):

C1 Functions in relation to Act transferred to Health Service Executive (1.01.2005) by *Health Act 2004* (42/2004), ss. 58, 59 and sch. 3, S.I. No. 887 of 2004.

Dissolution of health boards and other specified bodies.

58.—The specified bodies are, by this Act, dissolved on the establishment day.

Transfer of functions of specified bodies to Executive.

59.—(1) The functions that, immediately before the establishment day, were the functions of a specified body under or in connection with the enactments referred to in Schedule 3 are, by this Act, transferred to the Executive on that day.

(2) If a provision of an enactment referred to in Schedule 3, or a provision of an instrument made under such enactment, does not come into effect until on or after the establishment day, a function that on the passing of that enactment or the making of that instrument was assigned under or in connection with that provision to a specified body is, by this Act, transferred to the Executive on the commencement of that provision.

(3) The functions transferred by this Act to the Executive include the functions specified in any enactment referred to in Schedule 3 as a function of the following:

(*a*) the chief executive officer of a health board;

(*b*) the Regional Chief Executive of the Eastern Regional Health Authority;

(*c*) the area chief executive of an Area Health Board.

...

SCHEDULE 3

Transfer of Functions and References to Functional Areas

Section 59 and 67

...

39. Irish Medicines Board Act 1995

...

C2 Application of Act extended (15.06.2000) by *Customs-Free Airport (Extension of Laws) Regulations 2000* (S.I. No. 169 of 2000), reg. 3.

3. The provisions of the *Irish Medicines Board Act 1995* (No 29 of 1995), together with any Regulations made under Section 32 thereof and any other Regulations in force for the time being by virtue of Section 34(4) of the said Act, are hereby extended to the Customs-free Airport at Shannon.

Interpretation.

1.—(1) In this Act unless the context otherwise requires—

F1**[**"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;**]**

F2**[**"authorised medicinal product" means a medicinal product that is authorised under the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007) or Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004[7], as amended;**]**

"the Board" means the Irish Medicines Board;

"the Chief Executive" means the chief executive officer of the Board;

"a committee" means a committee appointed under *section 9*;

"cosmetic product" has the meaning assigned to it by Council Directive No. 93/35/EEC of 14 June 1993[1];

F1**[**"drug precursor" means a scheduled substance as defined in Article 2 of Council Regulation (EC) No. 111/2005 of 22 December 2004[1];**]**

"the establishment day" means the day appointed by the Minister under *section 2*;

"the former Board" means the National Drugs Advisory Board established under the Health (Corporate Bodies) Act, 1961;

"functions" includes powers and duties and references to the performance of functions includes as respects powers and duties, references to the exercise of the powers and the carrying out of the duties;

F3**[**"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;**]**

[7] OJ L136, 30.4.2004, p.1
[1] OJ. No. L151, 23.6.93, p.32
[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

F2**[**"medicinal product shortage" means where the current or anticipated supply of an authorised medicinal product or products that is placed on the market does not meet the current or, as the case may be, anticipated demand for that medicinal product or products;**]**

F2**[**"medicinal product that is in short supply" means, in relation to a medicinal product shortage, the authorised medicinal product or products that is the subject of the medicinal product shortage;**]**

"the Minister" means the Minister for Health;

F1**[**"premises" includes any aircraft, hovercraft, ship, stall or vehicle;**]**

F2**[**"protocol" means a protocol issued by the Minister under *section 32G*;**]**

"recognised trade unions and staff associations" means the trade unions and staff associations recognised by the Board for the purpose of negotiations which are concerned with the remuneration, conditions of employment or working conditions of officers of the Board and employees of the F3**[**Board;**]**

F1**[**"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;

F2**[**"registered pharmacist" means a person registered in the register of pharmacists established under section 13 of the Pharmacy Act 2007;**]**

F2**[**"substitutable medicinal product" means the medicinal product or products that registered pharmacists are authorised under a protocol to supply in substitution for the medicinal product that is in short supply;**]**

"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.**]**

(2) In this Act—

(*a*) a reference to any enactment shall, unless the context otherwise requires, be construed as a reference to that enactment as amended or extended by or under any subsequent enactment including this Act,

(*b*) a reference to a section is a reference to a section of this Act unless it is indicated that reference to some other enactment is intended,

(*c*) a reference to a subsection, paragraph or subparagraph is a reference to the subsection, paragraph or subparagraph of the provision in which the reference occurs unless it is indicated that reference to some other provision is intended.

Annotations

Amendments:

F1 Inserted (22.07.2007) by *Irish Medicines Board (Miscellaneous Provisions) Act 2006* (3/2006), s. 10(a), (b), (d), (f), S.I. No. 543 of 2007.

F2 Inserted (1.01.2025) by *Health (Miscellaneous Provisions) Act 2024* (23/2024), s. 8, S.I. No. 753 of 2024.

F3 Substituted (22.07.2007) by *Irish Medicines Board (Miscellaneous Provisions) Act 2006* (3/2006), s. 10(c), (e), S.I. No. 543 of 2007.

[6] OJ L311, 28.11.2001, p.1

Modifications (not altering text):

C3 References to a "registered medical practitioner" construed (3.07.2008) by *Medical Practitioners Act 2007* (25/2007), s. 108(1), S.I. No. 231 of 2008.

Construction of references to registered medical practitioner and Medical Council, etc.

108.— (1) Every reference to a registered medical practitioner contained in any enactment or any statutory instrument shall be construed as a reference to a registered medical practitioner within the meaning of section 2.

...

Establishment day.

2.—The Minister may by order appoint a day to be the establishment day for the purposes of this Act.

Annotations

Editorial Notes:

E1 Power pursuant to section exercised (1.01.1996) by *Irish Medicines Board Act 1995 (Establishment) Order 1995* (S.I. No. 346 of 1995).

2. The establishment day as provided for in section 2 of the Irish Medicines Board Act 1995 shall be the 1st day of January, 1996.

Establishment of Irish Medicines Board.

3.—(1) On the establishment day there shall stand established a board to be known as the Irish Medicines Board (in this Act referred to as "the Board") to perform the functions conferred on it by or under this Act.

(2) The Board shall be a body corporate with perpetual succession and an official seal and power to sue and be sued in its corporate name and, with the consent of the Minister, to acquire, hold and dispose of land or an interest in land and to acquire, hold and dispose of any other property.

(3) The Board shall, subject to the provisions of this Act, be independent in the exercise of its functions.

F4**[**(4) The body that, immediately before the commencement of section 36 of the Health (Pricing and Supply of Medical Goods) Act 2013, was known as the Irish Medicines Board shall, from such commencement, cease to be known by that name and instead be known as the Health Products Regulatory Authority.**]**

Annotations

Amendments:

F4 Inserted (1.07.2014) by *Health (Pricing and Supply of Medical Goods) Act 2013* (14/2013), s. 36, S.I. No. 205 of 2014.

Functions of Board.

4.—(1) F5**[**Subject to *subsection (4)*, the**]** principal functions of the Board shall be—

(*a*) the licensing of the manufacture, preparation, importation, distribution and sale of medicinal products,

F5**[**(*b*) to exercise the powers conferred on the competent authority by Directive No. 2001/83/EC of 6 November 2001[5], F6**[**other than those powers conferred by Article 5.3 of the said Directive,**]**

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

[5] OJ L311, 28.11.2001, p.67
[7] OJ L136, 30.04.2004, p.1

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

(*e*) to exercise the powers specified in the Control of Clinical Trials Acts, 1987 and 1990, and conferred on the Board by *section 35*,

(*f*) to establish and administer a service for obtaining and assessing information as regards the safety, quality and efficacy of medicinal products,

(*g*) to establish and administer a service for obtaining and assessing reports on any adverse effects of medicinal products in use in the State,

(*h*) to advise the Minister and others concerned as to the precautions or restrictions, if any, subject to which medicinal products may be marketed or continued in use in the State,

(*i*) to arrange for the collection and dissemination of information relating to medicinal products including, in particular, information concerning the pharmacological classification and therapeutic efficacy of such products,

(*j*) to furnish, whenever it is so requested by the Minister, advice to the Minister in relation to the licensing of the manufacture, importation, distribution and sale of medicinal products and in relation to the standards of manufacturing practice (including quality control) of medicinal products,

F7**[**(*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

(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,**]**

(*l*) to establish and administer a service for the inspection of any service for the collection, screening, processing and quality control facilities and procedures in respect of human blood, blood components, blood products and plasma derivatives for the purpose of ensuring the safety and quality of blood, blood components, blood products and plasma derivatives and to advise the Minister in relation to such general or particular matters arising out of the administration of such a service as the Minister may refer to the Board,

(*m*) if so requested, to advise the Minister or others concerned on such matters relating to medical devices as may be referred to it and are connected with the functions or activities of, or the services provided by, the Board,

(*n*) to furnish, whenever it so thinks fit or is so requested by the Minister, advice to the Minister in relation to any matter connected with the functions or activities of, or the services provided by, the Board.

F8**[**(*o*) to exercise the powers conferred on the competent authority by Council Directive 98/79/EC of the 27th October, 1998[3] and the European Communities (In Vitro Diagnostic Medical Devices) Regulations, 2001**]**

F9**[**(*p*) to exercise the powers conferred on the competent authority by Council Directive 90/385/EEC of 20 June 1990[4] and the European Communities

[3] OJ No. L331 7.12.1998, p.1.
[4] OJ No. L189 20.7.1990, p. 0017 - 0036

(Active Implantable Medical Devices) Regulations, 1994 (S.I. No. 253 of 1994) and Council Directive 93/42/EC of 14 June 1993[5] and the European Communities (Medical Devices) Regulations, 1994 (S.I. No. 252 of F10**[**1994),**]]**

F11**[**(*q*) ...**]**

F12**[**(*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],**]**

F13**[**(*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),**]**

F12**[**(*u*) to exercise the powers conferred on the competent authority by Directive 2004/23/EC of 31 March 2004[11],

F14**[**(*v*) to exercise the powers conferred on the competent authority and the authority responsible for notified bodies by Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017[1] and carry out the functions conferred on the Authority under Regulation 3(3)(a) of the European Union (Medical Devices and In Vitro Diagnostic Medical Devices) Regulations 2017 (S.I. No. 547 of 2017),

(*w*) to exercise the powers conferred on the competent authority and the authority responsible for notified bodies by Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017[2] and carry out the functions conferred on the Authority under Regulation 3(3)(b) of the European Union (Medical Devices and In Vitro Diagnostic Medical Devices) Regulations 2017 (S.I. No. 547 of 2017),

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

(2) The Board shall also have and enjoy all those functions that were vested in the former Board immediately before the establishment day and are not specified in *subsection (1)*.

(3) The Board shall have all such powers as are necessary or expedient for the performance of its functions.

F5**[**(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.**]**

[5] OJ No. L169 12.7.1993, p.1.
[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, 07.04.2004, p.48
[1] OJ No. L 117, 5.5.2017, p. 1.
[2] OJ No. L 117, 5.5.2017, p. 176.

Annotations

Amendments:

F5 Substituted (22.07.2007) by *Irish Medicines Board (Miscellaneous Provisions) Act 2006* (3/2006), s. 11(a)(i),(ii), (b), S.I. No. 543 of 2007.

F6 Inserted (23.07.2007) by *European Communities (Amendment of the Irish Medicines Board Act 1995) Regulations 2007* (S.I. No. 542 of 2007), reg. 3, in operation as per reg. 2.

F7 Substituted (22.07.2007) by *Irish Medicines Board (Miscellaneous Provisions) Act 2006* (3/2006), s. 11(a)(iii), S.I. No. 543 of 2007, other than insofar as it relates to cosmetic products and (1.10.2010), S.I. No. 441 of 2010, in so far as it relates to cosmetic products.

F8 Inserted (29.06.2001) by *European Communities (In Vitro Diagnostic Medical Devices) Regulations 2001* (S.I. No. 304 of 2001), reg. 3(1).

F9 Inserted (1.10.2001) by *European Communities (Medical Devices) (Amendment) Regulations 2001* (S.I. No. 444 of 2001), reg. 2(1), in operation as per reg. 3.

F10 Substituted (1.10.2010) by *Irish Medicines Board (Miscellaneous Provisions) Act 2006* (3/2006), s. 11(a)(iv), S.I. No. 441 of 2010.

F11 Inserted by *Irish Medicines Board (Miscellaneous Provisions) Act 2006* (3/2006), s. 11(a)(v), not commenced as of date of revision.

F12 Inserted (1.12.2013) by *Irish Medicines Board (Miscellaneous Provisions) Act 2006* (3/2006), s. 11(a)(v), S.I. No. 453 of 2013.

F13 Inserted (1.10.2010) by *Irish Medicines Board (Miscellaneous Provisions) Act 2006* (3/2006), s. 11(a)(v), S.I. No. 441 of 2010.

F14 Substituted and inserted (4.12.2017) by *European Union (Medical Devices and In Vitro Diagnostic Medical Devices) Regulations 2017* (S.I. No. 547 of 2017), reg. 4.

Modifications (not altering text):

C4 Prospective affecting provision: subs. (1)(q) inserted by *Irish Medicines Board (Miscellaneous Provisions) Act 2006* (3/2006), s. 11(a)(v), not commenced as of date of revision.

...

F11**[**(*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),**]**

...

Editorial Notes:

E2 Power pursuant to subs. (4) exercised (6.05.1998) by *Irish Medicines Board (Competent Authority) Order 1998* (S.I. No. 143 of 1998).

Conferral of additional functions on Board.

5.—(1) The Minister may, if he or she so thinks fit or, if so requested by the Minister for Agriculture, Food and Forestry, by order—

(*a*) confer on the Board such additional functions connected with the functions for the time being of the Board or the services or activities that the Board is authorised for the time being to provide or carry on (including functions for the purpose of giving effect to any directive, regulation or other act adopted by an institution of the European Communities in relation to medicinal products F15**[**, veterinary medicinal products, cosmetic products, drug precursors or medical devices**]**) as he or she considers appropriate, and

(*b*) make such provision as he or she considers necessary or expedient in relation to matters ancillary to or arising out of the conferral on the Board of functions under this section or the performance by the Board of functions so conferred.

(2) The Minister may by order amend or revoke an order under this section (including an order under this subsection).

Annotations

Amendments:

F15 Inserted (22.07.2007) by *Irish Medicines Board (Miscellaneous Provisions) Act 2006* (3/2006), s. 12, S.I. No. 543 of 2007.

Chairperson of Board.

6.—(1) The Minister shall appoint a member of the Board to be chairperson of the Board.

(2) Where the chairperson of the Board ceases to be a member of the Board he or she shall also thereupon cease to be chairperson of the Board.

(3) The chairperson of the Board may at any time resign his or her office as chairperson by letter sent to the Minister and the resignation shall, unless previously withdrawn in writing, take effect at the commencement of the meeting of the Board held next after the Board has been informed by the Minister of the resignation.

(4) The chairperson of the Board shall, unless he or she sooner dies or otherwise ceases to be chairperson by virtue of *subsection (2)* or *(3)*, hold office until the expiration of his or her period of membership of the Board but, if he or she is re-appointed as a member of the Board, he or she shall be eligible for re-appointment as chairperson of the Board.

(5) F16**[**...**]**

Annotations

Amendments:

F16 Deleted (16.02.2017) by *Health (Miscellaneous Provisions) Act 2017* (1/2017), s. 3, commenced on enactment.

Members of Board.

7.—(1) The number of members of the Board shall be 9.

(2) The Minister shall, as soon as may be after the establishment day, appoint persons to be members of the Board.

(3) Except as provided for by the preceding subsection, the members of the Board shall be appointed from time to time as occasion requires by the Minister.

(4) The Minister when appointing a member shall fix such member's period of membership which shall not exceed 5 years and, subject to this section, membership shall be on such terms as the Minister determines.

(5) A member of the Board may at any time resign his or her membership by letter addressed to the Minister and the resignation shall take effect from the date specified therein or upon receipt of the letter by the Minister, whichever is the later.

(6) A member of the Board may at any time be removed from membership of the Board by the Minister if, in the Minister's opinion, the member has become incapable through ill-health of performing his or her functions, or has committed stated misbehaviour, or his or her removal appears to the Minister to be necessary for the effective performance by the Board of its functions.

(7) If a member of the Board dies, resigns, becomes disqualified or is removed from office, the Minister may appoint a person to be a member of the Board to fill the casual vacancy so occasioned.

(8) A member of the Board whose period of membership expires by the effluxion of time shall be eligible for re-appointment as a member of the Board.

F17**[**(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.**]**

Annotations

Amendments:

F17 Substituted (22.07.2007) by *Irish Medicines Board (Miscellaneous Provisions) Act 2006* (3/2006), s. 13, S.I. No. 543 of 2007.

F18**[**Remuneration and allowances for expenses of members of Health Products Regulatory Authority

7A. A member of the Health Products Regulatory Authority shall be paid, out of moneys at the disposal of the Authority, such remuneration (if any) and such allowances for expenses as the Minister, with the consent of the Minister for Public Expenditure and Reform, may from time to time determine.**]**

Annotations

Amendments:

F18 Inserted (16.02.2017) by *Health (Miscellaneous Provisions) Act 2017* (1/2017), s. 4, commenced on enactment.

Editorial Notes:

E3 The section heading is taken from the amending section in the absence of one included in the amendment.

Meetings of Board.

8.—(1) The Board shall hold such and as many meetings as may be necessary for the performance of its functions.

(2) The Minister shall fix the date, time and place of the first meeting of the Board.

(3) The quorum for a meeting of the Board shall be 5.

(4) At a meeting of the Board—

(*a*) the chairperson of the Board shall, if present, be the chairperson of the meeting, and

(*b*) if and so long as the chairperson of the Board is not present or if the office of the chairperson is vacant, the members of the Board who are present shall choose one of their members to be chairperson of the meeting.

(5) At a meeting of the Board, each member of the Board present shall have a vote and every question shall be determined by a majority of votes of the members present and voting on the question and, in the case of an equal division of votes, the chairperson of the meeting shall have a casting vote.

(6) The Board may act notwithstanding one or more vacancies among its members.

(7) F19**[**...**]**

(8) Subject to the provisions of this Act, the Board shall regulate, by standing orders or otherwise, the procedure and business of the Board.

(9) The Board shall, as soon as may be after its establishment, provide itself with a seal.

(10) The seal of the Board shall be authenticated by the signature of its chairperson or another member of the Board authorised by it to act in that behalf and by the signature of an officer of the Board authorised by it to act in that behalf.

(11) Judicial notice shall be taken of the seal of the Board and every document purporting to be an instrument made by the Board and to be sealed with the seal (purporting to be authenticated in accordance with *subsection (10)*) of the Board shall be received in evidence and be deemed to be such instrument without proof unless the contrary is shown.

Annotations

Amendments:

F19 Deleted (16.02.2017) by *Health (Miscellaneous Provisions) Act 2017* (1/2017), s. 5, commenced on enactment.

Advisory committees.

9.—(1) The Minister shall, as soon as may be after the establishment day, appoint—

(*a*) a committee to be known as the Advisory Committee for Human Medicines to assist and advise the Board in relation to any matters pertaining to the safety, quality or efficacy of medicinal products for human use as are referred to it by the Board and to perform the functions assigned to it by *subsection (8)*, and

(*b*) a committee to be known as the Advisory Committee for Veterinary Medicines to assist and advise the Board in relation to any matters pertaining to the safety, quality or efficacy of medicinal products for animal use as are referred to it by the Board and to perform the functions assigned to it by *subsection (8)*.

F20**[**(*c*) a committee to be known as the Advisory Committee for Medical Devices to assist and advise the Board in relation to any matters pertaining to the safety, quality and efficacy of medical devices as are referred to it by the Board.**]**

(2) The members of a committee shall be appointed by the Minister, with, in the case of the committee referred to in *paragraph (b)*, the consent of the Minister for Agriculture, Food and Forestry, and the number of such members shall be not less than 6 nor more than 12.

(3) The Minister shall appoint a chairperson of a committee from amongst the members of the committee.

(4) The Minister when appointing a member shall fix such member's period of membership which shall not exceed 5 years and, subject to this section, membership shall be on such terms as the Minister determines.

(5) A committee shall regulate, by standing orders or otherwise, the procedure and business of the committee.

(6) (*a*) A committee may from time to time establish subcommittees to advise it in relation to the performance of its functions.

(*b*) A committee may appoint to a subcommittee established under this subsection persons who have a special knowledge and experience related to the purposes of the subcommittee.

(*c*) The appointment of a person to a subcommittee established under this subsection shall be subject to such terms and conditions as a committee may determine.

(*d*) A committee may at any time dissolve a subcommittee established under this subsection.

(*e*) The acts of a subcommittee established under this subsection shall be subject to confirmation by a committee unless the committee dispenses with the necessity for confirmation.

(*f*) A committee may regulate the procedure of subcommittees established under this subsection, but, subject to any such regulation, subcommittees established under this subsection may regulate their own procedure.

(*g*) A committee shall notify the Minister of the establishment of a subcommittee, of the purpose of the subcommittee and of the names of the members thereof.

(*h*) The Minister may, if he or she considers it appropriate, appoint additional persons to be members of any subcommittee.

(7) There may be paid by the Board to members of a committee and to members of any subcommittee established under this section such allowances for expenses incurred by them as the Board may, with the consent of the Minister and the Minister for Finance, determine.

F21**[**(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.**]**

F22**[**(10) In *subsections (8)* and *(9)*, any reference to a medicinal product includes a reference to a medicinal product for animal use.**]**

Annotations

Amendments:

F20 Inserted (11.12.2002) by *European Communities (Medical Devices) (Amendment) Regulations 2002* (S.I. No. 576 of 2002), reg. 3.

F21 Substituted (22.07.2007) by *Irish Medicines Board (Miscellaneous Provisions) Act 2006* (3/2006), s. 14(a), S.I. No. 543 of 2007.

F22 Inserted (22.07.2007) by *Irish Medicines Board (Miscellaneous Provisions) Act 2006* (3/2006), s. 14(b), S.I. No. 543 of 2007.

Modifications (not altering text):

C5 Functions transferred and references to "Department of Finance" and "Minister for Finance" construed (29.07.2011) by *Finance (Transfer of Departmental Administration and Ministerial Functions) Order 2011* (S.I. No. 418 of 2011), arts. 2, 3, 5 and sch. 1 part 2, in operation as per art. 1(2).

...

2. (1) The administration and business in connection with the performance of any functions transferred by this Order are transferred to the Department of Public Expenditure and Reform.

(2) References to the Department of Finance contained in any Act or instrument made thereunder and relating to the administration and business transferred by paragraph (1) shall, on and after the commencement of this Order, be construed as references to the Department of Public Expenditure and Reform.

3. The functions conferred on the Minister for Finance by or under the provisions of —

(*a*) the enactments specified in Schedule 1, and

(*b*) the statutory instruments specified in Schedule 2,

are transferred to the Minister for Public Expenditure and Reform.

...

5. References to the Minister for Finance contained in any Act or instrument under an Act and relating to any functions transferred by this Order shall, from the commencement of this Order, be construed as references to the Minister for Public Expenditure and Reform.

...

Schedule 1

Enactments

...

Part 2

1922 to 2011 Enactment

Number and Year (1)	Short Title (2)	Provision (3)
...	...	...
No. 29 of 1995	Irish Medicines Board Act 1995	Sections 9(7), 13(3) and 15
...	...	...

Chief Executive.

10.—(1) There shall be a chief executive officer of the Board who shall be known, and is referred to in this Act, as the Chief Executive.

(2) The Chief Executive shall be appointed and may be removed from office at any time for stated reasons by the Board with the consent of the Minister.

(3) The Chief Executive shall carry on and manage and control generally the administration and business of the Board and perform such other functions as may be determined by the Board.

(4) The Chief Executive shall hold office for such term and upon and subject to such other terms and conditions (including terms and conditions relating to remuneration) as may be determined by the Minister after consultation with the Board and with the consent of the Minister for Finance.

(5) The Board shall act through, and its functions shall be performed in the name of the Board by, the Chief Executive or another officer of the Board duly authorised in that behalf by the Chief Executive.

(6) The Chief Executive shall not be a civil servant within the meaning of the Civil Service Regulation Act, 1956.

(7) The Chief Executive may make proposals to the Board on any matter relating to its activities.

(8) The Chief Executive shall devote the whole of his or her time to his or her duties as Chief Executive and shall not hold any other office or position without the consent of the Board.

(9) The Chief Executive shall not be a member of the Board or of a committee or subcommittee appointed under *section 9*.

(10) In this section "remuneration" includes allowances for expenses, benefits-in-kind and superannuation.

Staff of Board.

11.—(1) The Board may appoint such and such number of persons to be members of the staff of the Board as it may determine with the consent of the Minister and the Minister for Finance.

(2) (*a*) A member of the staff of the Board (other than the Chief Executive) shall be paid, out of moneys at the disposal of the Board, such remuneration and allowances for expenses incurred by him or her as the Board may, with the consent of the Minister and the Minister for Finance, determine.

(*b*) A member of the staff of the Board shall hold his or her office or employment on such other terms and conditions as the Board may, with the consent of the Minister and the Minister for Finance, determine.

(3) The grades of the staff of the Board and the numbers of staff in each grade shall be determined by the Board with the consent of the Minister and the Minister for Finance.

(4) Every person who immediately before the establishment day is a member of the staff of the former Board shall, on that day, be transferred to, and become a member of the staff of, the Board.

(5) The terms and conditions relating to tenure of office which are granted by the Board in relation to a member of the staff of the Board who is transferred by *subsection (4)* to its staff from the former Board shall not, while he or she is in the service of the Board, be less favourable to him or her than those prevailing immediately before the establishment day in the former Board save in accordance with a collective agreement negotiated with any recognised trade unions or staff associations concerned.

(6) Save in accordance with a collective agreement negotiated with any recognised trade unions or staff associations concerned, a member of the staff of the former Board who is transferred by *subsection (4)* to the staff of the Board shall not, while in the service of the Board, receive a lesser scale of pay or be made subject to less beneficial terms and conditions of service (other than those relating to tenure of office) than the scale of pay to which he or she was entitled and the terms and conditions of service (other than those relating to tenure of office) to which he or she was subject immediately before the establishment day.

(7) Until such time as the scales of pay and terms and conditions of service (other than those relating to tenure of office) of staff so transferred are varied by the Board, following consultation with any recognised trade unions and staff associations concerned, the scales of pay to which they were entitled and the terms and conditions of service (other than those relating to tenure of office), restrictions, requirements and obligations to which they were subject immediately before their transfer shall continue to apply to them and may be applied or imposed by the Board or the Chief Executive, as the case may be, while they are in the service of the Board and no such variation shall operate to worsen the scales of pay or the terms or conditions of service aforesaid applicable to a member of such staff immediately before the establishment day, save in accordance with a collective agreement negotiated with any recognised trade unions or staff associations concerned.

(8) In relation to staff transferred by *subsection (4)* to the staff of the Board, previous service in, or service reckonable for the purposes of any superannuation benefits payable by or on behalf of, the former Board shall be reckonable for the purposes of, but subject to any other exceptions or exclusions in, the Redundancy Payments Acts, 1967 to 1984, the Holidays (Employees) Act, 1973, the Minimum Notice and Terms of Employment Acts, 1973 to 1991, the Unfair Dismissals Acts, 1977 to 1993 and the Terms of Employment (Information) Act, 1994.

Superannuation of staff of Board.

12.—The Local Government (Superannuation) Act, 1980, shall apply to the Board and members of its staff as if it were a body to which section 3 of the said Act applied and they were members of the staff of such a body but subject to any modifications (including modifications to any scheme or regulations made under

the said Act) which may, with the consent of the Minister for the Environment, be specified in an order made by the Minister.

Fees.

13.—F23**[**(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.**]**

(2) Where under regulations under this section a fee is payable in respect of any F23**[**matter or application, the matter or application**]** shall be invalid and shall not be decided or otherwise dealt with, as may be appropriate, by the Board unless the Board is in receipt of the fee.

(3) Fees received by the Board under this Act shall be paid into or disposed of for the benefit of the Exchequer in such manner as the Minister for Finance directs.

(4) The Public Offices Fees Act, 1879, shall not apply to any fees charged under this Act.

F24**[**(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.**]**

Annotations

Amendments:

F23 Substituted (22.07.2007) by *Irish Medicines Board (Miscellaneous Provisions) Act 2006* (3/2006), s. 15(a), (b), S.I. No. 543 of 2007.

F24 Inserted (22.07.2007) by *Irish Medicines Board (Miscellaneous Provisions) Act 2006* (3/2006), s. 15(c), S.I. No. 543 of 2007.

Modifications (not altering text):

C6 Power of Board to charge fees extended (20.11.2013) by *European Union (Cosmetic Products) Regulations 2013* (S.I. No. 440 of 2013), reg. 3(6).

Responsibility for functions under EU Regulation

3. (1) The national competent authority for the purposes of the EU Regulation shall be the Board.

...

(6) The Board may charge fees for its functions under the EU Regulation in accordance with regulations made under section 13(1) of the Act, read in conjunction with section 4(1)(v) of the Act.

...

C7 Power of Board to charge fees extended (1.01.2013) by *European Union (Protection of Animals used for Scientific Purposes) Regulations 2012* (S.I. No. 543 of 2012), reg. 5(3).

Responsibility for functions under Directive

5. (1) Subject to paragraph (2), the functions of the State and of the competent authority under the Directive shall be performed by the IMB.

...

(3) The IMB may charge fees for its functions under the Directive and these Regulations in accordance with regulations made under s. 13(1) of the Act, read in conjunction with s. 4(1)(v) of the Act.

...

C8 Functions transferred and references to "Department of Finance" and "Minister for Finance" construed (29.07.2011) by *Finance (Transfer of Departmental Administration and Ministerial Functions) Order 2011* (S.I. No. 418 of 2011), arts. 2, 3, 5 and sch. 1 part 2, in operation as per art. 1(2).

2. (1) The administration and business in connection with the performance of any functions transferred by this Order are transferred to the Department of Public Expenditure and Reform.

(2) References to the Department of Finance contained in any Act or instrument made thereunder and relating to the administration and business transferred by paragraph (1) shall, on and after the commencement of this Order, be construed as references to the Department of Public Expenditure and Reform.

3. The functions conferred on the Minister for Finance by or under the provisions of —

(*a*) the enactments specified in Schedule 1, and

(*b*) the statutory instruments specified in Schedule 2,

are transferred to the Minister for Public Expenditure and Reform.

...

5. References to the Minister for Finance contained in any Act or instrument under an Act and relating to any functions transferred by this Order shall, from the commencement of this Order, be construed as references to the Minister for Public Expenditure and Reform.

...

Schedule 1

Enactments

...

Part 2

1922 to 2011 Enactments

Number and Year (1)	Short Title (2)	Provision (3)
...	...	...
No. 29 of 1995	Irish Medicines Board Act 1995	Sections 9(7), 13(3) and 15
...	...	...

Editorial Notes:

E4 Power pursuant to section exercised (17.12.2025) by *Health Products Regulatory Authority (Fees) Regulations 2025* (S.I. No. 624 of 2025).

E5 Previous affecting provision: power pursuant to section exercised (23.12.2024) by *Health Products Regulatory Authority (Fees) Regulations 2024* (S.I. No. 751 of 2024); revoked (17.12.2025) by *Health Products Regulatory Authority (Fees) Regulations 2025* (S.I. No. 624 of 2025), reg. 5.

E6 Previous affecting provision: power pursuant to section exercised (21.12.2023) by *Health Products Regulatory Authority (Fees) Regulations 2023* (S.I. No. 697 of 2023); revoked (23.12.2024) by *Health Products Regulatory Authority (Fees) Regulations 2024* (S.I. No. 751 of 2024), reg. 5.

E7 Previous affecting provision: power pursuant to section exercised (15.12.2022) by *Health Products Regulatory Authority (Fees) Regulations 2022* (S.I. No. 679 of 2022); revoked (21.12.2023) by *Health Products Regulatory Authority (Fees) Regulations 2023* (S.I. No. 697 of 2023), reg. 5.

E8 Previous affecting provision: power pursuant to section exercised (21.12.2021) by *Health Products Regulatory Authority (Fees) Regulations 2021* (S.I. No. 744 of 2021); revoked (15.12.2022) by *Health Products Regulatory Authority (Fees) Regulations 2022* (S.I. No. 679 of 2022), reg. 5.

E9 Previous affecting provision: power pursuant to section exercised (17.12.2020) by *Health Products Regulatory Authority (Fees) Regulations 2020* (S.I. No. 654 of 2020); revoked (21.12.2021) by *Health Products Regulatory Authority (Fees) Regulations 2021* (S.I. No. 744 of 2021), reg. 5.

E10 Previous effecting provision: power pursuant to section exercised (20.12.2019) by *Health Products Regulatory Authority (Fees) Regulations 2019* (S.I. No. 700 of 2019); revoked (17.12.2020) by *Health Products Regulatory Authority (Fees) Regulations 2020* (S.I. No. 654 of 2020), reg. 5.

E11 Previous affecting provision: power pursuant to section exercised (11.12.2018) by *Health Products Regulatory Authority (Fees) (No. 2) Regulations 2018* (S.I. No. 531 of 2018); revoked (20.12.2019) by *Health Products Regulatory Authority (Fees) Regulations 2019* (S.I. No. 700 of 2019), reg. 5.

E12 Previous affecting provision: power pursuant to section exercised (19.06.2018) by *Health Products Regulatory Authority (Fees) Regulations 2018* (S.I. No. 208 of 2018); revoked (11.12.2018) by *Health Products Regulatory Authority (Fees) (No. 2) Regulations 2018* (S.I. No. 531 of 2018), reg. 5.

E13 Previous affecting provision: power pursuant to section exercised (5.12.2017) by *Health Products Regulatory Authority (Fees) Regulations 2017* (S.I. No. 557 of 2017); revoked (19.06.2018) by *Health Products Regulatory Authority (Fees) Regulations 2018* (S.I. No. 208 of 2018), reg. 5.

E14 Previous affecting provision: power pursuant to section exercised (6.12.2016) by *Health Products Regulatory Authority (Fees) Regulations 2016* (S.I. No. 602 of 2016); revoked (5.12.2017) by *Health Products Regulatory Authority (Fees) Regulations 2017* (S.I. No. 557 of 2017), reg. 5.

E15 Previous affecting provision: power pursuant to section exercised (17.12.2015) by *Health Products Regulatory Authority (Fees) Regulations 2015* (S.I. No. 599 of 2015); revoked (6.12.2016) by *Health Products Regulatory Authority (Fees) Regulations 2016* (S.I. No. 602 of 2016), reg. 5.

E16 Previous affecting provision: power pursuant to section exercised (23.12.2014) by *Health Products Regulatory Authority (Fees) Regulations 2014* (S.I. No. 607 of 2014); revoked (17.12.2015) by *Health Products Regulatory Authority (Fees) Regulations 2015* (S.I. No. 599 of 2015), reg. 5.

E17 Previous affecting provision: power pursuant to section exercised (17.12.2013) by *Irish Medicines Board (Fees) Regulations 2013* (S.I. No. 501 of 2013); revoked (23.12.2014) by *Health Products Regulatory Authority (Fees) Regulations 2014* (S.I. No. 607 of 2014), reg. 5.

E18 Previous affecting provision: power pursuant to section exercised (22.05.2013) by *Irish Medicines Board (Fees) (Amendment) Regulations 2013* (S.I. No. 165 of 2013); revoked (17.12.2013) by *Irish Medicines Board (Fees) Regulations 2013* (S.I. No. 501 of 2013), reg. 5.

E19 Previous affecting provision: power pursuant to section exercised (21.12.2012) by *Irish Medicines Board (Fees) Regulations 2012* (S.I. No. 572 of 2012); revoked (17.12.2013) by *Irish Medicines Board (Fees) Regulations 2013* (S.I. No. 501 of 2013), reg. 5.

E20 Previous affecting provision: power pursuant to section exercised (21.12.2011) by *Irish Medicines Board (Fees) Regulations 2011* (S.I. No. 684 of 2011); revoked (21.12.2012) by *Irish Medicines Board (Fees) Regulations 2012* (S.I. No. 572 of 2012), reg. 5.

E21 Previous affecting provision: power pursuant to section exercised (22.12.2010) by *Irish Medicines Board (Fees) Regulations 2010* (S.I. No. 632 of 2010); revoked (21.12.2011) by *Irish Medicines Board (Fees) Regulations 2011* (S.I. No. 684 of 2011), reg. 5.

E22 Previous affecting provision: power pursuant to section exercised (1.01.2010) by *Irish Medicines Board (Fees) Regulations 2009* (S.I. No. 551 of 2009), in operation as per reg. 2; revoked (22.12.2010) by *Irish Medicines Board (Fees) Regulations 2010* (S.I. No. 632 of 2010), reg. 5.

E23 Previous affecting provision: power pursuant to section exercised (1.01.2009) by *Irish Medicines Board (Fees) Regulations 2008* (S.I. No. 542 of 2008), in operation as per reg. 2; revoked (1.01.2010) by *Irish Medicines Board (Fees) Regulations 2009* (S.I. No. 551 of 2009), reg. 5, in operation as per reg. 2.

E24 Previous affecting provision: power pursuant to section exercised (1.01.2008) by *Irish Medicines Board (Fees) Regulations 2007* (S.I. No. 866 of 2007), in operation as per reg. 2; revoked (1.01.2008) by *Irish Medicines Board (Fees) Regulations 2008* (S.I. No. 542 of 2008), reg. 7, in operation as per reg. 2.

E25 Previous affecting provision: power pursuant to section exercised (1.01.2007) by *Irish Medicines Board (Fees) Regulations 2006* (S.I. No. 617 of 2006), in operation as per reg. 2; revoked (1.01.2008) by *Irish Medicines Board (Fees) Regulations 2007* (S.I. No. 866 of 2007), reg. 7.

E26 Previous affecting provision: power pursuant to section exercised (1.01.2006) by *Irish Medicines Board (Fees) Regulations 2005* (S.I. No. 882 of 2005), in operation as per reg. 2; revoked (1.01.2007) by *Irish Medicines Board (Fees) Regulations 2006* (S.I. No. 617 of 2006), reg. 7, in operation as per reg. 2.

E27 Previous affecting provision: power pursuant to section exercised (1.01.2005) by *Irish Medicines Board (Fees) Regulations 2004* (S.I. No. 877 of 2004), in operation as per reg. 2; revoked (1.01.2006) by *Irish Medicines Board (Fees) Regulations 2005* (S.I. No. 882 of 2005), reg. 7, in operation as per reg. 2.

E28 Previous affecting provision: power pursuant to section exercised (31.08.2004) by *Irish Medicines Board (Fees) (Amendment) Regulations 2004* (S.I. No. 524 of 2004); revoked (1.01.2005) by *Irish Medicines Board (Fees) Regulations 2004* (S.I. No. 877 of 2004), reg. 7, in operation as per reg. 2.

E29 Previous affecting provision: power pursuant to section exercised (1.01.2004) by *Irish Medicines Board (Fees) Regulations 2003* (S.I. No. 731 of 2003), in operation as per reg. 2; revoked (1.01.2005) by *Irish Medicines Board (Fees) Regulations 2004* (S.I. No. 877 of 2004), reg. 7, in operation as per reg. 2.

E30 Previous affecting provision: power pursuant to section exercised (1.06.2002) by *Irish Medicines Board (Fees) (Medicinal Products For Human Use) Regulations 2002* (S.I. No. 262 of 2002), in operation as per reg. 2; revoked (1.01.2004) by *Irish Medicines Board (Fees) Regulations 2003* (S.I. No. 731 of 2003), reg. 7, in operation as per reg. 2.

E31 Previous affecting provision: power pursuant to section exercised (1.08.2000) by *Irish Medicines Board (Fees) (Amendment) Regulations 2000* (S.I. No. 233 of 2000), in operation as per reg. 3; revoked (1.06.2002) by *Irish Medicines Board (Fees) (Medicinal Products For Human Use) Regulations 2002* (S.I. No. 262 of 2002), reg. 7, in operation as per reg. 2.

E32 Previous affecting provision: exercised (19.02.1996) by *Irish Medicines Board (Fees) Regulations 1996* (S.I. No. 44 of 1996), in operation as per reg. 5; revoked (1.06.2002) by *Irish Medicines Board (Fees) (Medicinal Products For Human Use) Regulations 2002* (S.I. No. 262 of 2002), reg. 7, in operation as per reg. 2.

Charges for services.

14.—(1) Subject to the provisions of this section, the Board may make such charges as it considers appropriate in consideration of the performance by it of its functions, the provision by it of services (other than a service consisting of the provision of advice for the Minister or the Minister for Agriculture, Food and Forestry) and the carrying on by it of activities and may sell, for such prices as it considers appropriate, anything produced by the Board and may enter into contracts, upon such terms and conditions as it considers appropriate.

(2) The determination of the amounts of charges by the Board for advisory services shall be subject to the approval of the Minister.

(3) Charges, prices and payments under *subsection (1)* in respect of functions performed, services provided, activities carried on or things sold, shall not, save with the approval of the Minister, be less than the cost of the performance of the function, the provision of the service, the carrying on of the activity or the production and development of the thing, as the case may be.

(4) The Board may recover, as a simple contract debt in any court of competent jurisdiction, from the person by whom it is payable any amount due and owing to it under *subsection (1)*.

Grants to Board.

15.—The Minister may, in each financial year, after consultation with the Board in relation to its proposed work programme and expenditure for that year, make grants of such amount as may be sanctioned by the Minister for Finance out of moneys provided by the Oireachtas towards the expenditure incurred by the Board in the performance of its functions.

Annotations

Modifications (not altering text):

C9 Functions transferred and references to "Department of Finance" and "Minister for Finance" construed (29.07.2011) by *Finance (Transfer of Departmental Administration and Ministerial Functions) Order 2011* (S.I. No. 418 of 2011), arts. 2, 3, 5 and sch. 1 part 2, in operation as per art. 1(2).

2. (1) The administration and business in connection with the performance of any functions transferred by this Order are transferred to the Department of Public Expenditure and Reform.

(2) References to the Department of Finance contained in any Act or instrument made thereunder and relating to the administration and business transferred by paragraph (1) shall, on and after the commencement of this Order, be construed as references to the Department of Public Expenditure and Reform.

3. The functions conferred on the Minister for Finance by or under the provisions of —

(*a*) the enactments specified in Schedule 1, and

(*b*) the statutory instruments specified in Schedule 2,

are transferred to the Minister for Public Expenditure and Reform.

...

5. References to the Minister for Finance contained in any Act or instrument under an Act and relating to any functions transferred by this Order shall, from the commencement of this Order, be construed as references to the Minister for Public Expenditure and Reform.

...

Schedule 1

Enactments

...

Part 2

1922 to 2011 Enactments

Number and Year	Short Title	Provision
(1)	(2)	(3)
...	...	...

No. 29 of 1995	Irish Medicines Board Act 1995	Sections 9(7), 13(3) and 15
...	...	...

Gifts.

16.—(1) The Board may accept gifts of money, land or other property, upon such trusts or conditions, if any, as may be specified by the donor.

(2) The Board shall not accept a gift if the trusts or conditions attached to it would be inconsistent with its functions.

Borrowing by Board.

17.—The Board may, for the purpose of providing for current or capital expenditure, from time to time, borrow money (whether on the security of the assets of the Board or otherwise), including money in a currency other than the currency of the State, but shall not do so without the consent of the Minister and the Minister for Finance.

Annotations

Modifications (not altering text):

C10 Functions under section transferred (6.07.2011) by *Ministers and Secretaries (Amendment) Act 2011* (10/2011), ss. 9(1), (2), 20(1) and sch. 2 part 1, S.I. No. 401 of 2011.

Transfer of certain other functions to Minister.

9.— (1) (*a*) Subject to *paragraph (b)*, the following functions of the Minister for Finance are transferred to the Minister, except in so far as they consist of the power to pay moneys out of the Central Fund:

(i) all functions (including functions conferred by or under statute) relating to superannuation, remuneration (including allowances and expenses), appointment and terms and conditions of service of members of staff of public service bodies;

(ii) all functions (including functions conferred by or under statute) relating to remuneration (including fees, allowances and expenses), appointment and terms and conditions of service of members, or members of boards, of public service bodies;

(iii) the functions consisting of the sanctioning or approval of expenses incurred in the administration of any statute;

...

(*b*) This subsection shall not effect the transfer to the Minister of functions of the Minister for Finance consisting of the superannuation or remuneration of members, members of boards, or members of staff of a body to which *section 21* applies.

(2) The functions conferred on the Minister for Finance by or under any of the provisions specified in *Part 1* of *Schedule 2* are transferred to the Minister.

...

Performance of certain functions transferred to Minister by *section 9*.

20.— (1) The Minister shall not perform a function transferred by *subsection (2)* of *section 9* without the consent of the Minister for Finance.

...

SCHEDULE 2

Functions Transferred To Minister

PART 1

Functions performable with consent of Minister for Finance

STATUTES

Number and Year (1)	Short Title (2)	Provision (3)
...	...	...
No. 29 of 1995	Irish Medicines Board Act 1995	Section 17
...	...	...

Accounts and audits of Board.

18.—(1) The Board shall submit estimates of income and expenditure to the Minister in such form, in respect of such periods, and at such times as may be required by him or her and shall furnish to the Minister any information which he or she may require in relation to such estimates.

(2) The Board shall cause to be kept on a continuous basis proper books of account of all income and expenditure of the Board, and of the sources of such income and the subject matter of such expenditure, and of the property, assets and liabilities of the Board and shall keep all such special accounts as the Minister may from time to time direct.

(3) The financial year of the Board shall be the period of twelve months ending on the 31st day of December in any year, and for the purposes of this provision the period commencing on the date of the commencement of this section and ending on the 31st December, 1995, shall be deemed to be a financial year.

(4) The expenses generally of such audit shall be paid by the Board as soon as may be after each audit.

(5) The Board and the officers thereof, shall, whenever so requested by the Minister, permit any person appointed by him to examine the books and accounts of the Board in respect of any financial year or other period and shall facilitate any such examination, and the Board shall pay such fee therefor as may be fixed by the Minister.

(6) The accounts of the Board for each year shall be prepared in such form and manner as may be specified by the Minister. The accounts shall be submitted as soon as may be but not later than 3 months after the end of the financial year to which they relate by the Board to the Comptroller and Auditor General for audit. A copy of the accounts and the auditor's report thereon shall be presented to the members of the Board and to the Minister as soon as may be and the Minister shall cause a copy of the documents aforesaid to be laid before each House of the Oireachtas.

Reports and information to Minister.

19.—(1) As soon as may be after the end of each financial year, but not later than 6 months thereafter, the Board shall make a report to the Minister of its activities during that year and the Minister shall cause copies of the report to be laid before each House of the Oireachtas.

(2) Each report under *subsection (1)* shall include information in such form and regarding such matters as the Minister may direct.

(3) The Board shall, whenever so requested by the Minister, furnish to the Minister information in relation to such matters as he or she may specify concerning or relating to the scope of its activities generally, or in respect of any account prepared by the Board or any report specified in *subsection (1)* or *section 18(6)* or the policy or activities, other than day to day activities, of the Board.

Assessment by Board of performance of certain of its functions.

20.—The Board shall, in each year, carry out such examinations as it considers appropriate for the purpose of ascertaining—

(*a*) whether and to what extent the resources of the Board—

(i) have been used, and

(ii) if acquired or disposed of by the Board, have been so acquired or disposed of,

economically and efficiently, and

(*b*) whether any such disposal has been effected upon the most favourable terms reasonably obtainable.

General duty of Board.

21.—It shall be the general duty of the Board so to conduct its affairs as to secure, as soon as may be, that, taking one year with another, the revenue of the Board shall be at least sufficient to meet the charges properly chargeable to revenue.

Membership of either House of Oireachtas or of European Parliament.

22.—(1) Where a member of the Board is—

(*a*) nominated as a member of Seanad Éireann, or

(*b*) elected as a member of either House of the Oireachtas or to the European Parliament, or

(*c*) regarded, pursuant to section 15 (inserted by the European Parliament Elections Act, 1993) of the European Assembly Elections Act, 1977, as having been elected to the European Parliament to fill a vacancy,

he or she shall thereupon cease to be a member of the Board.

(2) Where a member of the staff of the Board is—

(*a*) nominated as a member of Seanad Éireann, or

(*b*) elected as a member of either House of the Oireachtas or to the European Parliament, or

(*c*) regarded, pursuant to the said section 15, as having been elected to the European Parliament to fill a vacancy, he or she shall thereupon stand seconded from his or her employment with the Board and shall not be paid by, or be entitled to receive from, the Board remuneration or allowances in respect of the period commencing on such nomination or election, or when he or she is so regarded as having been elected (as the case may be) and ending when he or she ceases to be a member of either such House or such Parliament.

(3) A person who is for the time being entitled under the Standing Orders of either House of the Oireachtas to sit therein or who is a member of the European Parliament shall, while he or she is so entitled or is such a member, be disqualified from becoming a member, or a member of the staff, of the Board.

(4) Without prejudice to the generality of *subsection (2)*, that subsection shall be construed as prohibiting, among other things, the reckoning of a period mentioned in that subsection as service with the Board for the purposes of any superannuation benefits.

Disclosure of information.

23.—(1) A person shall not, without the consent of the Board, disclose any information obtained by him or her while performing (or as a result of having performed) duties as a member, or member of the staff of, or an adviser or consultant to, the Board.

(2) A person who contravenes *subsection (1)* shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding £1,500.

(3) Nothing in *subsection (1)* shall prevent the disclosure of information in a report made to the Board or by or on behalf of the Board to the Minister.

Annotations

Modifications (not altering text):

C11 Person holding record under section excluded from requirement to refuse an FOI request (14.10.2014) by *Freedom of Information Act 2014* (30/2014), s. 32 and sch. 3 part 1, commenced as per s. 1(2).

Enactments relating to non-disclosure of records

41. (1) A head shall refuse to grant an FOI request if—

(*a*) the disclosure of the record concerned is prohibited by law of the European Union or any enactment (other than a provision specified in column (3) of *Part 1* or *2* of *Schedule 3* of an enactment specified in that Schedule), or

...

SCHEDULE 3

Enactments Excluded from Application of *Section 41*

Part 1

Statutes

...

No. 29 of 1995 Irish Medicines Board Act 1995, section 23.

...

Editorial Notes:

E33 A fine of £1,500 converted (1.01.1999) to €1,904.61. This translates into a class B fine, not greater than €4,000, as provided (4.01.2011) by *Fines Act 2010* (8/2010), ss. 3, 5(2) and table ref. no. 2, S.I. No. 662 of 2010.

E34 Previous affecting provision: person holding record under section excluded from requirement to refuse an FOI request (21.04.1998) by *Freedom of Information Act 1997* (13/1997), s. 41(1)(a) and sch. 3 part 1, commenced on enactment.

Disclosure of interests.

24.—(1) Where the Chief Executive, a member of the Board, an employee of the Board, a member of a committee or of a subcommittee established under *section 9*, a consultant, adviser or other person engaged by the Board, has a pecuniary or other beneficial interest in, or material to, any matter which falls to be considered by the Board, a committee or a subcommittee, he or she shall comply with the following requirements—

(*a*) he or she shall disclose to the Board, committee or subcommittee, as the case may be, the nature of his or her interest in advance of any consideration of the matter,

(*b*) he or she shall neither influence nor seek to influence a decision in relation to the matter,

(*c*) he or she shall take no part in any consideration of the matter,

(*d*) if he or she is the Chief Executive of the Board, a member of the Board, an employee of the Board or a member of a committee or subcommittee established under *section 9*, he or she shall withdraw from the meeting for so long as the matter is being discussed or considered by the Board, committee or subcommittee and shall not vote or otherwise act as such Chief Executive or member in relation to the matter.

(2) For the purposes of this section, but without prejudice to the generality of *subsection (1)*, a person shall be regarded as having a beneficial interest if—

(*a*) he or she or any member of his or her household, or any nominee of his or her or any member of his or her household, is a member of a company or any other body which has a beneficial interest in, or material to, a matter referred to in that subsection,

(*b*) he or she or any member of his or her household is in partnership with or is in the employment of a person who has a beneficial interest in, or material to, such a matter,

(*c*) he or she or any member of his or her household is a party to any arrangement or agreement (whether or not enforceable) concerning land to which such a matter relates,

(*d*) any member of his or her household has a beneficial interest in, or material to, such a matter.

(3) For the purposes of this section a person shall not be regarded as having a beneficial interest in, or material to, any matter by reason only of an interest of his or her or of any company or of any other body or person mentioned in *subsection (2)* which is so remote or insignificant that it cannot reasonably be regarded as likely to influence a person in considering, discussing or in voting on, any question with respect to the matter, or in performing any function in relation to that matter.

(4) Where a question arises as to whether or not a course of conduct, if pursued by a person, would be a failure by him to comply with the requirements of *subsection (1)*, the question shall be determined by the Board and particulars of the determination shall be recorded in the minutes of the meeting concerned.

(5) Where a disclosure is made to the Board, a committee or a subcommittee pursuant to *subsection (1)*, particulars of the disclosure shall be recorded in the minutes of the meeting concerned.

(6) A person who contravenes *subsection (1)* shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding £1,500 or to imprisonment for a term not exceeding one year or to both.

Annotations

Editorial Notes:

E35 A fine of £1,500 converted (1.01.1999) to €1,904.61. This translates into a class B fine, not greater than €4,000, as provided (4.01.2011) by *Fines Act 2010* (8/2010), ss. 3, 5(2) and table ref. no. 2, S.I. No. 662 of 2010.

Dissolution of former Board.

25.—(1) The former Board shall, on the establishment day, become and be dissolved.

(2) References in any Act of the Oireachtas passed before the establishment day or in any instrument made before that day under an Act of the Oireachtas to the former Board shall, on and after that day, be construed as references to the Board.

Transfer of assets and liabilities of former Board.

26.—(1) The following shall be and hereby are transferred to the Board on the establishment day—

(*a*) all property and rights relating to such property held or enjoyed immediately before that day by the former Board or any trustee or agent thereof acting on its behalf, and

(*b*) all liabilities incurred before that day by the former Board or any trustee or agent thereof acting on its behalf that had not been discharged before that day,

and, accordingly, without any further conveyance, transfer or assignment—

(i) the said property, real and personal, shall, on that day, vest in the Board for all the estate, term or interest for which, immediately before that day, it was so vested in the former Board, as the case may be, but subject to all trusts and equities affecting the property and capable of being performed,

(ii) the said rights shall, as on and from that day, be enjoyed by the Board, and

(iii) the said liabilities shall, as on and from that day, be liabilities of the Board.

(2) All moneys, stocks, shares and securities transferred to the Board by this section that, on the establishment day, are standing in the name of the former Board or any said trustee or agent thereof shall, upon the request of the Board, be transferred into its name.

(3) Every right and liability transferred to the Board by this section may, on or after the establishment day, be sued on, recovered or enforced by or against the Board in its own name and it shall not be necessary for the Board to give notice to the person whose right or liability is transferred by this section of the transfer.

Preservation of certain continuing contracts and adaptation of references to former Board.

27.—(1) Every bond, guarantee or other security of a continuing nature made or given by or on behalf of the former Board to any person or given by any person to and accepted by or on behalf of the former Board and every contract or agreement made between the former Board, or any trustee or agent thereof acting on its behalf, and any other person and in force but not fully executed and completed immediately before the establishment day shall continue in force on or after that day and shall be construed and have effect as if the name of the Board was substituted therein for that of the former Board or, as appropriate, its said trustee or agent and shall be enforceable by or against the Board.

(2) References to the former Board, or any trustee or agent thereof acting on its behalf, contained immediately before the establishment day in the memorandum and articles of association of any company shall, on and after that day, be construed as references to the Board.

Saving for certain acts.

28.—Nothing in this Act shall affect the validity of any act that was done before the establishment day by or on behalf of the former Board and every such act shall, if and in so far as it was operative immediately before that day, have effect on and after that day as if it had been done by or on behalf of the Board.

Pending legal proceedings.

29.—Where, immediately before the establishment day, any legal proceedings are pending in any court or tribunal and the former Board, or any trustee or agent thereof acting on its behalf, is a party to the proceedings, the name of the Board shall be substituted therein for that of the former Board or, as appropriate, the said trustee or agent thereof and the proceedings shall not abate by reason of such substitution.

Exemption from stamp duty.

30.— F25**[**...**]**

Annotations

Amendments:

F25 Repealed (25.03.1999) by *Finance Act 1999* (2/1999), s. 197 and sch. 6 col. 3, commenced on enactment.

Completion of certain matters commenced by Minister or by former Board.

31.—Anything commenced by the Minister before the establishment day pursuant to powers conferred on him or her by section 65 of the Health Act, 1947, may be carried on and completed on and after that day by the Board and anything commenced by the former Board before that day may be carried on and completed on and after that day by the Board.

Regulations.

32.—(1) The Minister may by regulations make such provision as he or she considers necessary or expedient for the purposes of this Act.

(2) Without prejudice to the generality of *subsection (1)*, regulations under this section may, in relation to medicinal products for human use F26**[**, cosmetic products or medical devices**]**, make provision for—

(*a*) the regulation (including the control) of the manufacture, production, preparation, importation, distribution, sale, supply, F27**[**administration,**]** placing on the market, advertisement or promotion of the product or products F27**[**, or the device or devices,**]** to which the regulations relate,

(*b*) the prohibition of the manufacture, preparation, importation, distribution, sale or offering or keeping for sale of the product or products F27**[**, or the device or devices,**]** to which the regulations relate either absolutely or subject to specified conditions (including the granting by the Board of licences for the manufacture, preparation, importation, distribution or sale of such product or products F27**[**or such device or devices**]**),

(*c*) the prohibition of the advertisement of the product or products F27**[**, or the device or devices,**]** to which the regulations relate either absolutely or subject to specified conditions (including the grant by the Board of a licence F26**[**, authorisation or certificate for such product or products or such device or devices**]**) and the prohibition of the sale or offering or keeping for sale of any such product F26**[**or products or such device or devices which is or are**]** advertised in contravention of such regulations,

(*d*) the regulation and control of the packaging and labelling of the product or products F27**[**, or the device or devices,**]** to which the regulations relate and, in particular, for the specification of information relating to such product or products F27**[**, or such device or devices,**]** to be contained on any packet used in the sale, supply or distribution of such product or products F27**[**, or such device or devices,**]** or on a label attached to such packet,

(*e*) the determination of the classes of persons to whom licences F27**[**, authorisations or certificates**]** under the regulations are to be granted,

(*f*) the specification of conditions for the grant, suspension, retention, amendment or renewal of licences F27**[**, authorisations or certificates**]** under the regulations,

(*g*) the refusal or revocation of licences F27**[**, authorisations or certificates**]** under the regulations,

(*h*) the requiring of applicants for or holders of licences F27**[**, authorisation or certificates**]** under the regulations to furnish specified information in regard to the constitution, manufacture, importation, storage, distribution, sale or advertisement of the product or products F27**[**, or the device or devices,**]** to which their applications or licences F27**[**, authorisations or certificates**]** relate,

F26**[**(*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—

F28**[**(i) by a registered pharmacist, or a person, or class of persons, specified in the regulations, being a suitably qualified person or class of persons—

(I) concerned in the provision of a health service, whether the health service is provided in a hospital, nursing home, clinic, retail pharmacy business (within the meaning of the Pharmacy Act 2007) or otherwise,

(II) registered with a relevant professional body, and

(III) trained in the administration of the medicinal product,

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 F28**[**thereto,**]**

(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,

F29**[**(iv) subject to *subsection (11A)*, such medicinal product or class of medicinal products as may be used for the purpose of treating mild or moderate illnesses or ailments, pursuant to a prescription issued by a registered pharmacist—

(I) who has reached the required standard of education and training in relation to prescribing medicinal products in accordance with the rules of the Council of the Pharmaceutical Society of Ireland made under section 11(3A) of the Pharmacy Act 2007,

(II) where the prescription is issued under the governance of a retail pharmacy business (within the meaning of the Pharmacy Act 2007) in accordance with regulations made under section 18 of the Pharmacy Act 2007, and

(III) in accordance with such other rules made, and codes of conduct drawn up by the Council of the Pharmaceutical Society of Ireland under sections 7(2)(a)(iii) and 11 of the Pharmacy Act 2007,

or

(v) subject to *subsection (11A)*, by a registered pharmacist, in accordance with such conditions 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.**]**

F26**[**(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—

(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.**]**

(5) An offence under this section may be prosecuted by the Minister, the Board, the Pharmaceutical Society of Ireland or the health board in whose functional area the offence is committed.

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

F27**[**(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

[12] OJ L311, 28.11.2001, p.67

(*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.

F29**[**(11A) Before making regulations under section *32(2)(l)(iv)* or *(v)*, the Minister shall consult the Health Service Executive and the Council of the Pharmaceutical Society of Ireland, and may consult any other person or body as he or she considers appropriate.**]**

(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.

F28**[**(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 section 16 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006 , 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 section 16 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006 , and in his or her capacity as such member, have lawfully issued a prescription for a medicinal product;

"relevant professional body" means—

(*a*) the Dental Council established under section 6 of the Dentists Act 1985,

(*b*) the Nursing and Midwifery Board of Ireland referred to in section 6 of the Nurses and Midwives Act 2011,

(*c*) the Optical Registration Board established by section 26 of the Health and Social Care Professionals Act 2005,

(*d*) the Physiotherapists Registration Board established by section 26 of the Health and Social Care Professionals Act 2005,

(*e*) the Podiatrists Registration Board established by section 26 of the Health and Social Care Professionals Act 2005,

(*f*) the Radiographers Registration Board established by section 26 of the Health and Social Care Professionals Act 2005, or

(*g*) the Pre-Hospital Emergency Care Council established by the Pre Hospital Emergency Care Council (Establishment) Order 2000 (S.I. No. 109 of 2000).**]]**

Annotations

Amendments:

F26 Substituted (1.05.2007) by *Irish Medicines Board (Miscellaneous Provisions) Act 2006* (3/2006), s. 16(a)(i), (iv)(II), (III), (viii), (b), S.I. No. 194 of 2007. A fine of €2,000 translates into a class C fine, not greater than €2,500, as provided (4.01.2011) by *Fines Act 2010* (8/2010), ss. 3, 6(3) and table ref. no. 1, S.I. No. 662 of 2010.

F27 Inserted (1.05.2007) by *Irish Medicines Board (Miscellaneous Provisions) Act 2006* (3/2006), s. 16(a)(ii)(I), (II), (iii)(I), (II), (iv)(I), (v)(I), (II), (vi), (vii)(I)-(III), (c), S.I. No. 194 of 2007.

F28 Substituted (1.01.2025) by *Health (Miscellaneous Provisions) Act 2024* (23/2024), s. 9(a)(i), (a)(ii)(I), (c), S.I. No. 753 of 2024.

F29 Inserted (1.01.2025) by *Health (Miscellaneous Provisions) Act 2024* (23/2024), s. 9(a)(ii)(II), (b), S.I. No. 753 of 2024.

Modifications (not altering text):

C12 References to "pharmaceutical chemist" construed (29.11.2008) by *Pharmacy Act 2007* (20/2007), s. 75, S.I. No. 487 of 2008.

Interpretation of references to pharmaceutical chemists, persons keeping open shop, etc.

75.— (1) Any reference (however expressed) in a prior enactment to a pharmaceutical chemist registered under the Pharmacy Act (Ireland) 1875 or a dispensing chemist and druggist registered under the Pharmacy Act 1951 shall be construed as a reference to a registered pharmacist.

(2) Any reference (however expressed) in a prior enactment to a person who is keeping open shop for the dispensing or compounding of medical prescriptions under the Pharmacy Acts 1875 to 1977—

(*a*) where that person is, in relation to a pharmacist, a representative within the meaning given by section 25 (2), shall be construed as a reference to such a representative, and

(*b*) in any other case, shall be construed as a reference to a registered retail pharmacy business.

...

C13 Application of Act extended (15.06.2000) by *Customs-Free Airport (Extension of Laws) Regulations 2000* (S.I. No. 169 of 2000), reg. 3.

3. The provisions of the *Irish Medicines Board Act 1995* (No 29 of 1995), together with any Regulations made under Section 32 thereof and any other Regulations in force for the time being by virtue of Section 34(4) of the said Act, are hereby extended to the Customs-free Airport at Shannon.

Editorial Notes:

E36 Power pursuant to section exercised (30.06.2026) by *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2026* (S.I. No. 138 of 2026), in operation as per reg. 3.

E37 Power pursuant to section exercised (17.12.2025) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2025* (S.I. No. 625 of 2025).

E38 Power pursuant to section exercised (17.12.2025) by *Health Products Regulatory Authority (Fees) Regulations 2025* (S.I. No. 624 of 2025).

E39 Power pursuant to section exercised (23.10.2025) by *Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2025* (S.I. No. 504 of 2025).

E40 Power pursuant to section exercised (22.10.2025) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 3) Regulations 2025* (S.I. No. 502 of 2025).

E41 Power pursuant to section exercised (1.09.2025) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2025* (S.I. No. 418 of 2025).

E42 Power pursuant to section exercised (22.07.2025) by *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2025* (S.I. No. 353 of 2025).

E43 Power pursuant to section exercised (31.10.2024) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 5) Regulations 2024* (S.I. No. 582 of 2024), in operation as per reg. 2.

E44 Power pursuant to section exercised (16.09.2024) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2024* (S.I. No. 458 of 2024), in operation as per reg. 2.

E45 Power pursuant to section exercised (22.04.2024) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 3) Regulations 2024* (S.I. No. 162 of 2024).

E46 Power pursuant to section exercised (1.03.2024) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2024* (S.I. No. 73 of 2024), in operation as per reg. 2.

E47 Power pursuant to section exercised (1.03.2024) by *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2024* (S.I. No. 72 of 2024), in operation as per reg. 2.

E48 Power pursuant to section exercised (21.12.2023) by *Health Products Regulatory Authority (Fees) Regulations 2023* (S.I. No. 697 of 2023).

E49 Power pursuant to section exercised (29.11.2023) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2023* (S.I. No. 584 of 2023).

E50 Power pursuant to section exercised (14.09.2023) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 6) Regulations 2023* (S.I. No. 451 of 2023).

E51 Power pursuant to section exercised (23.08.2023) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 5) Regulations 2023* (S.I. No. 422 of 2023).

E52 Power pursuant to section exercised (1.06.2023) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2023* (S.I. No. 284 of 2023).

E53 Power pursuant to section exercised (16.05.2023) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 3) Regulations 2023* (S.I. No. 238 of 2023).

E54 Power pursuant to section exercised (7.03.2023) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2023* (S.I. No. 105 of 2023).

E55 Power pursuant to section exercised (23.01.2023) by *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2023* (S.I. No. 11 of 2023).

E56 Power pursuant to section exercised (20.09.2022) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 5) Regulations 2022* (S.I. No. 467 of 2022).

E57 Power pursuant to section exercised (29.07.2022) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2022* (S.I. No. 402 of 2022).

E58 Power pursuant to section exercised (14.07.2022) by *In Vitro Diagnostic Medical Devices (Registration) Regulations 2022* (S.I. No. 365 of 2022).

E59 Power pursuant to section exercised (1.06.2022) by *Medicinal Products (Safety Features on Packaging) Regulations 2022* (S.I. No. 270 of 2022).

E60 Power pursuant to section exercised (26.05.2022) by *In Vitro Diagnostic Medical Devices Regulations 2022* (S.I. No. 256 of 2022), in operation as per reg. 2.

E61 Power pursuant to section exercised (24.02.2022) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 3) Regulations 2022* (S.I. No. 84 of 2022).

E62 Power pursuant to section exercised (15.02.2022) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2022* (S.I. No. 57 of 2022).

E63 Power pursuant to section exercised (31.01.2022) by *Medicinal Products (Control of Manufacture) (Amendment) Regulations 2022* (S.I. No. 43 of 2022).

E64 Power pursuant to section exercised (1.01.2022, deemed) by *Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2022* (S.I. No. 416 of 2022).

E65 Power pursuant to section exercised (1.01.2022, deemed) by *Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2022* (S.I. No. 415 of 2022).

E66 Power pursuant to section exercised (1.01.2022, deemed) by *Medicinal Products (Control of Manufacture) (Amendment) (No. 2) Regulations 2022* (S.I. No. 414 of 2022).

E67 Power pursuant to section exercised (25.01.2022) by *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2022* (S.I. No. 32 of 2022).

E68 Power pursuant to section exercised (16.12.2021) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 15) Regulations 2021* (S.I. No. 718 of 2021).

E69 Power pursuant to section exercised (9.12.2021) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 14) Regulations 2021* (S.I. No. 692 of 2021).

E70 Power pursuant to section exercised (9.12.2021) by *Medical Devices (Registration) Regulations 2021* (S.I. No. 691 of 2021).

E71 Power pursuant to section exercised (19.11.2021) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 13) Regulations 2021* (S.I. No. 605 of 2021).

E72 Power pursuant to section exercised (5.11.2021) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 12) Regulations 2021* (S.I. No. 578 of 2021).

E73 Power pursuant to section exercised (27.10.2021) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 11) Regulations 2021* (S.I. No. 558 of 2021).

E74 Power pursuant to section exercised (7.10.2021) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 10) Regulations 2021* (S.I. No. 511 of 2021).

E75 Power pursuant to section exercised (7.10.2021) by *Medical Devices (Amendment) Regulations 2021* (S.I. No. 510 of 2021).

E76 Power pursuant to section exercised (28.09.2021) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 9) Regulations 2021* (S.I. No. 492 of 2021).

E77 Power pursuant to section exercised (30.07.2021) by *Medicinal Products (Prescription and Control of Supply) (Amendment) No. 8 Regulations 2021* (S.I. No. 411 of 2021).

E78 Power pursuant to section exercised (26.05.2021) by *Medical Devices Regulations 2021* (S.I. No. 261 of 2021).

E79 Power pursuant to section exercised (13.05.2021) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2021* (S.I. No. 245 of 2021).

E80 Power pursuant to section exercised (31.03.2021) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 6) Regulations 2021* (S.I. No. 155 of 2021).

E81 Power pursuant to section exercised (23.03.2021) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 5) Regulations 2021* (S.I. No. 130 of 2021).

E82 Power pursuant to section exercised (23.02.2021) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2021* (S.I. No. 81 of 2021).

E83 Power pursuant to section exercised (4.02.2021) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 3) Regulations 2021* (S.I. No. 43 of 2021).

E84 Power pursuant to section exercised (13.01.2021) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2021* (S.I. No. 8 of 2021).

E85 Power pursuant to section exercised (4.01.2021) by *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2021* (S.I. No. 2 of 2021).

E86 Power pursuant to section exercised (4.01.2021) by *Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2021* (S.I. No. 1 of 2021).

E87 Power pursuant to section exercised (1.01.2021) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 6) Regulations 2020* (S.I. No. 614 of 2020), in operation as per reg. 2.

E88 Power pursuant to section exercised (24.12.2020) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020* (S.I. No. 698 of 2020).

E89 Power pursuant to section exercised (30.09.2020) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 5) Regulations 2020* (S.I. No. 401 of 2020).

E90 Power pursuant to section exercised (3.07.2020) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2020* (S.I. No. 241 of 2020).

E91 Power pursuant to section exercised (4.06.2020) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 3) Regulations 2020* (S.I. No. 204 of 2020).

E92 Power pursuant to section exercised (15.05.2020) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2020* (S.I. No. 177 of 2020).

E93 Power pursuant to section exercised (2.04.2020) by *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2020* (S.I. No. 98 of 2020).

E94 Power pursuant to section exercised (15.05.2019) by *Medicinal Products (Control of Manufacture) (Amendment) Regulations 2019* (S.I. No. 219 of 2019).

E95 Power pursuant to section exercised (15.05.2019) by *Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2019* (S.I. No. 218 of 2019).

E96 Power pursuant to section exercised (15.05.2019) by *Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2019* (S.I. No. 217 of 2019).

E97 Power pursuant to section exercised (9.02.2019) by *Medicinal Products (Safety Features On Packaging) Regulations 2019* (S.I. No. 36 of 2019).

E98 Power pursuant to section exercised (11.12.2018) by *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2018* (S.I. No. 530 of 2018).

E99 Power pursuant to section exercised (11.12.2018) by *Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2018* (S.I. No. 529 of 2018).

E100 Power pursuant to section exercised (15.10.2015) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2015* (S.I. No. 449 of 2015).

E101 Power pursuant to section exercised (24.06.2015) by *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2015* (S.I. No. 87 of 2015).

E102 Power pursuant to section exercised (5.11.2014) by *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2014* (S.I. No. 504 of 2014).

E103 Power pursuant to section exercised (2.07.2014) by *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2014* (S.I. No. 300 of 2014).

E104 Power pursuant to section exercised (26.03.2014) by *Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2014* (S.I. No. 151 of 2014).

E105 Power pursuant to section exercised (22.05.2013) by *Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2013* (S.I. No. 164 of 2013).

E106 Power pursuant to section exercised (22.05.2013) by *Medicinal Products (Control of Manufacture) (Amendment) Regulations 2013* (S.I. No. 163 of 2013).

E107 Power pursuant to section exercised (22.05.2013) by *Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2013* (S.I. No. 162 of 2013).

E108 Power pursuant to section exercised (25.07.2012) by *Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2012* (S.I. No. 274 of 2012).

E109 Power pursuant to section501 exercised (25.07.2012) by *Medicinal Products (Control of Manufacture) (Amendment) Regulations 2012* (S.I. No. 273 of 2012).

E110 Power pursuant to section exercised (25.07.2012) by *Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2012* (S.I. No. 272 of 2012).

E111 Power pursuant to section exercised (22.12.2011) by *Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2011* (S.I. No. 722 of 2011).

E112 Power pursuant to section exercised (14.10.2011) by *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2011* (S.I. No. 525 of 2011).

E113 Power pursuant to section exercised (11.06.2010) by *Medicinal Products (Control of Manufacture) Regulations 2007 (Amendment) Regulations 2010* (S.I. No. 288 of 2010), in operation as per reg. 3.

E114 Power pursuant to section exercised (11.06.2010) by *Medicinal Products (Control of Placing on the Market) Regulations 2007 (Amendment) Regulations 2010* (S.I. No. 287 of 2010), in operation as per reg. 3.

E115 Power pursuant to section exercised (11.06.2010) by *Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (Amendment) Regulations 2010* (S.I. No. 286 of 2010), in operation as per reg. 3.

E116 Power pursuant to section exercised (1.01.2010) by *Medicinal Products (Control of Placing On the Market) Regulations 2007 (Amendment) (No. 2) Regulations 2009* (S.I. No. 553 of 2009), in operation as per reg. 6.

E117 Power pursuant to section exercised (6.11.2009) by *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2009* (S.I. No. 442 of 2009).

E118 Power pursuant to section exercised (14.01.2009) by *Medicinal Products (Control of Manufacture) Regulations 2007 (Amendment) Regulations 2009* (S.I. No. 4 of 2009), in operation as per reg. 3.

E119 Power pursuant to section exercised (14.01.2009) by *Medicinal Products (Control of Placing On the Market) Regulations 2007 (Amendment) Regulations 2009* (S.I. No. 3 of 2009), in operation as per reg. 3.

E120 Power pursuant to section exercised (14.01.2009) by*Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (Amendment) Regulations 2009* (S.I. No. 2 of 2009), in operation as per reg. 3.

E121 Power pursuant to section exercised (1.12.2008) by *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2008* (S.I. No. 512 of 2008), in operation as per reg. 2(1).

E122 Power pursuant to section exercised (23.07.2007) by *Medicinal Products (Control of Advertising) Regulations 2007* (S.I. No. 541 of 2007), in operation as per reg. 2.

E123 Power pursuant to section exercised (23.07.2007) by *Medicinal Products (Control of Placing on the Market) Regulations 2007* (S.I. No. 540 of 2007), in operation as per reg. 2.

E124 Power pursuant to section exercised (23.07.2007) by *Medicinal Products (Control of Manufacture) Regulations 2007* (S.I. No. 539 of 2007), in operation as per reg. 2.

E125 Power pursuant to section exercised (23.07.2007) by *Medicinal Products (Control of Wholesale Distribution) Regulations 2007* (S.I. No. 538 of 2007), in operation as per reg. 2.

E126 Power pursuant to section exercised (1.05.2007) by *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007* (S.I. No. 201 of 2007).

E127 Power pursuant to section exercised (1.04.2007) by *Medicinal Products (Revocation of the Medical Preparations (Control of Amphetamine) Regulations 1969) Regulations 2007* (S.I. No. 99 of 2007), in operation as per reg. 2.

E128 Power pursuant to section exercised (9.08.2005) by *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2005* (S.I. No. 510 of 2005).

E129 Power pursuant to section exercised (18.10.2004) by *Medicinal Products (Amendment) Regulations 2004* (S.I. No. 663 of 2004).

E130 Power pursuant to section exercised (11.11.2003) by *Medicinal Products (Prescription and Control of Supply) Regulations 2003* (S.I. No. 540 of 2003), in operation as per reg. 2.

E131 Power pursuant to section exercised (14.11.2001) by *Medicinal Products (Licensing and Sale) (Amendment) Regulations 2001* (S.I. No. 512 of 2001).

E132 Power pursuant to section exercised (17.06.1999) by *Medicinal Products (Amendment) Regulations 1999* (S.I. No. 188 of 1999).

E133 Power pursuant to section exercised (17.06.1999) by *Medical Preparations (Labelling and Package Leaflets) (Amendment) Regulations 1999* (S.I. No. 187 of 1999).

E134 Power pursuant to section exercised (19.02.1996) by *Medical Preparations (Wholesale Licences) (Amendment) Regulations 1996* (S.I. No. 41 of 1996), in operation as per reg. 5.

E135 Previous affecting provision: power pursuant to section exercised (23.12.2024) by *Health Products Regulatory Authority (Fees) Regulations 2024* (S.I. No. 751 of 2024); revoked (17.12.2025) by *Health Products Regulatory Authority (Fees) Regulations 2025* (S.I. No. 624 of 2025), reg. 5.

E136 Previous affecting provision: power pursuant to section exercised (15.12.2022) by *Health Products Regulatory Authority (Fees) Regulations 2022* (S.I. No. 679 of 2022); revoked (21.12.2023) by *Health Products Regulatory Authority (Fees) Regulations 2023* (S.I. No. 697 of 2023), reg. 5.

E137 Previous affecting provision: power pursuant to section exercised (21.12.2021) by *Health Products Regulatory Authority (Fees) Regulations 2021* (S.I. No. 744 of 2021); revoked (15.12.2022) by *Health Products Regulatory Authority (Fees) Regulations 2022* (S.I. No. 679 of 2022), reg. 5.

E138 Previous affecting provision: power pursuant to section exercised (17.12.2020) by *Health Products Regulatory Authority (Fees) Regulations 2020* (S.I. No. 654 of 2020); revoked (21.12.2021) by *Health Products Regulatory Authority (Fees) Regulations 2021* (S.I. No. 744 of 2021), reg. 5.

E139 Previous affecting provision: power pursuant to section exercised (20.12.2019) by *Health Products Regulatory Authority (Fees) Regulations 2019* (S.I. No. 700 of 2019); revoked (17.12.2020) by *Health Products Regulatory Authority (Fees) Regulations 2020* (S.I. No. 654 of 2020), reg. 5.

E140 Previous affecting provision: power pursuant to section exercised (11.12.2018) by *Health Products Regulatory Authority (Fees) (No. 2) Regulations 2018* (S.I. No. 531 of 2018); revoked (20.12.2019) by *Health Products Regulatory Authority (Fees) Regulations 2019* (S.I. No. 700 of 2019), reg. 5.

E141 Previous affecting provision: power pursuant to section exercised (19.06.2018) by *Health Products Regulatory Authority (Fees) Regulations 2018* (S.I. No. 208 of 2018); revoked (11.12.2018) by *Health Products Regulatory Authority (Fees) (No. 2) Regulations 2018* (S.I. No. 531 of 2018), reg. 5.

E142 Previous affecting provision: power pursuant to section exercised (5.12.2017) by *Health Products Regulatory Authority (Fees) Regulations 2017* (S.I. No. 557 of 2017); revoked (19.06.2018) by *Health Products Regulatory Authority (Fees) Regulations 2018* (S.I. No. 208 of 2018), reg. 5.

E143 Previous affecting provision: power pursuant to section exercised (6.12.2016) by *Health Products Regulatory Authority (Fees) Regulations 2016* (S.I. No. 602 of 2016); revoked (5.12.2017) by *Health Products Regulatory Authority (Fees) Regulations 2017* (S.I. No. 557 of 2017), reg. 5.

E144 Previous affecting provision: power pursuant to section exercised (17.12.2015) by *Health Products Regulatory Authority (Fees) Regulations 2015* (S.I. No. 599 of 2015); revoked (6.12.2016) by *Health Products Regulatory Authority (Fees) Regulations 2016* (S.I. No. 602 of 2016), reg. 5.

E145 Previous affecting provision: power pursuant to section exercised (23.12.2014) by *Health Products Regulatory Authority (Fees) Regulations 2014* (S.I. No. 607 of 2014); revoked (17.12.2015) by *Health Products Regulatory Authority (Fees) Regulations 2015* (S.I. No. 599 of 2015), reg. 5.

E146 Previous affecting provision: power pursuant to section exercised (17.12.2013) by *Irish Medicines Board (Fees) Regulations 2013* (S.I. No. 501 of 2013); revoked (23.12.2014) by *Health Products Regulatory Authority (Fees) Regulations 2014* (S.I. No. 607 of 2014), reg. 5.

E147 Previous affecting provision: power pursuant to section exercised (22.05.2013) by *Irish Medicines Board (Fees) (Amendment) Regulations 2013* (S.I. No. 165 of 2013); revoked (17.12.2013) by *Irish Medicines Board (Fees) Regulations 2013* (S.I. No. 501 of 2013), reg. 5.

E148 Previous affecting provision: power pursuant to section exercised (21.12.2012) by *Irish Medicines Board (Fees) Regulations 2012* (S.I. No. 572 of 2012); revoked (17.12.2013) by *Irish Medicines Board (Fees) Regulations 2013* (S.I. No. 501 of 2013), reg. 5.

E149 Previous affecting provision: power pursuant to section exercised (1.07.2012) by *European Communities (In Vitro Diagnostic Medical Devices) (Amendment) Regulations 2012* (S.I. No. 207 of 2012); revoked (26.05.2022) by *In Vitro Diagnostic Medical Devices Regulations 2022* (S.I. No. 256 of 2022), reg. 37(c).

E150 Previous affecting provision: power pursuant to section exercised (21.12.2011) by *Irish Medicines Board (Fees) Regulations 2011* (S.I. No. 684 of 2011); revoked (21.12.2012) by *Irish Medicines Board (Fees) Regulations 2012* (S.I. No. 572 of 2012), reg. 5.

E151 Previous affecting provision: power pursuant to section exercised (22.12.2010) by *Irish Medicines Board (Fees) Regulations 2010* (S.I. No. 632 of 2010); revoked (21.12.2011) by *Irish Medicines Board (Fees) Regulations 2011* (S.I. No. 684 of 2011), reg. 5.

E152 Previously affecting provision: power pursuant to section exercised (1.01.2010) by *Irish Medicines Board (Fees) Regulations 2009* (S.I. No. 551 of 2009); revoked (22.12.2010) by *Irish Medicines Board (Fees) Regulations 2010* (S.I. No. 632 of 2010), reg. 5.

E153 Previously affecting provision: power pursuant to section exercised (1.01.2009) by *Irish Medicines Board (Fees) Regulations 2008* (S.I. No. 542 of 2008); revoked (1.01.2010) by *Irish Medicines Board (Fees) Regulations 2009* (S.I. No. 551 of 2009), reg. 7.

E154 Previous affecting provision: power pursuant to section exercised (1.01.2008) by *Irish Medicines Board (Fees) Regulations 2007* (S.I. No. 866 of 2007), in operation as per reg. 2; revoked (1.01.2009) by *Irish Medicines Board (Fees) Regulations 2008* (S.I. No. 542 of 2008), reg. 7, in operation as per reg. 2.

E155 Previous affecting provision: power pursuant to section exercised (1.01.2007) by *Irish Medicines Board (Fees) Regulations 2006* (S.I. No. 617 of 2006), in operation as per reg. 2; revoked (1.01.2008) by *Irish Medicines Board (Fees) Regulations 2007* (S.I. No. 866 of 2007), reg. 7, in operation as per reg. 2.

E156 Previous affecting provision: power pursuant to section exercised (1.01.2006) by *Irish Medicines Board (Fees) Regulations 2005* (S.I. No. 882 of 2005), in operation as per reg. 2; revoked (1.01.2007) by *Irish Medicines Board (Fees) Regulations 2006* (S.I. No. 617 of 2006), reg. 7, in operation as per reg. 2.

E157 Previous affecting provision: power pursuant to section exercised (1.01.2005) by *Irish Medicines Board (Fees) Regulations 2004* (S.I. No. 877 of 2004), in operation as per reg. 2; revoked (1.01.2006) by *Irish Medicines Board (Fees) Regulations 2005* (S.I. No. 882 of 2005), reg. 7, in operation as per reg. 2.

E158 Previous affecting provision: power pursuant to section exercised (31.08.2004) by *Irish Medicines Board (Fees) (Amendment) Regulations 2004* (S.I. No. 524 of 2004); revoked (1.01.2005) by *Irish Medicines Board (Fees) Regulations 2004* (S.I. No. 877 of 2004), reg. 7, in operation as per reg. 2.

E159 Previous affecting provision: power pursuant to section exercised (1.01.2004) by *Irish Medicines Board (Fees) Regulations 2003* (S.I. No. 731 of 2003), in operation as per reg. 2; revoked (1.01.2005) by *Irish Medicines Board (Fees) Regulations 2004* (S.I. No. 877 of 2004), reg. 7, in operation as per reg. 2.

E160 Previous affecting provision: power pursuant to section exercised (18.12.2002) by *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2002* (S.I. No. 627 of 2002), in operation as per reg. 3; revoked (11.11.2003) by *Medicinal Products (Prescription and Control of Supply) Regulations 2003* (S.I. No. 540 of 2003), reg. 3, in operation as per reg. 2.

E161 Previous affecting provision: power pursuant to section exercised (1.06.2002) by *Irish Medicines Board (Fees) (Medicinal Products For Human Use) Regulations 2002* (S.I. No. 262 of 2002), in operation as per reg. 2; revoked (1.01.2004) by *Irish Medicines Board (Fees) Regulations 2003* (S.I. No. 731 of 2003), reg. 7, in operation as per reg. 2.

E162 Previous affecting provision: power pursuant to section exercised (1.10.2001) by *Medicinal Products (Control of Paracetamol) Regulations 2001* (S.I. No. 150 of 2001), in operation as per reg. 2; revoked (11.11.2003) by *Medicinal Products (Prescription and Control of Supply) Regulations 2003* (S.I. No. 540 of 2003), reg. 3, in operation as per reg. 2.

E163 Previous affecting provision: power pursuant to section exercised (3.05.2000) by *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2000* (S.I. No. 116 of 2000); revoked (11.11.2003) by *Medicinal Products (Prescription and Control of Supply) Regulations 2003* (S.I. No. 540 of 2003), reg. 3, in operation as per reg. 2.

E164 Previous affecting provision: power pursuant to section exercised (1.09.1999) by *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 1999* (S.I. No. 271 of 1999), in operation as per reg. 3(1); revoked (11.11.2003) by *Medicinal Products (Prescription and Control of Supply) Regulations 2003* (S.I. No. 540 of 2003), reg. 3, in operation as per reg. 2.

E165 Previous affecting provision: power pursuant to section exercised (6.05.1998) by *Medicinal Products (Licensing and Sale) Regulations 1998* (S.I. No. 142 of 1998); revoked (23.07.2007) by *Medicinal Products (Control of Placing on the Market) Regulations 2007* (S.I. No. 540 of 2007), reg. 26(1), in operation as per reg. 2.

E166 Previous affecting provision: power pursuant to section exercised (15.10.1996) by *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 1996* (S.I. No. 309 of 1996); revoked (11.11.2003) by *Medicinal Products (Prescription and Control of Supply) Regulations 2003* (S.I. No. 540 of 2003), reg. 3, in operation as per reg. 2.

E167 Previous affecting provision: power pursuant to section exercised (15.10.1996) by *Medical Preparations (Advertising) (Amendment) Regulations 1996* (S.I. No. 308 of 1996); revoked (23.07.2007) by *Medicinal Products (Control of Advertising) Regulations 2007* (S.I. No. 541 of 2007), reg. 3, in operation as per reg. 2.

E168 Previous affecting provision: power pursuant to section exercised (1.09.1996) by *Medicinal Products (Prescription and Control of Supply) Regulations 1996* (S.I. No. 256 of 1996), in operation as per reg. 2; revoked (11.11.2003) by *Medicinal Products (Prescription and Control of Supply) Regulations 2003* (S.I. No. 540 of 2003), reg. 3, in operation as per reg. 2.

E169 Previous affecting provision: power pursuant to section exercised (19.02.1996) by *Medical Preparations (Licensing and Sale) Regulations 1996* (S.I. No. 43 of 1996), in operation as per reg. 16; revoked (6.05.1998) by *Medicinal Products (Licensing and Sale) Regulations 1998* (S.I. No. 142 of 1998), reg. 15.

E170 Previous affecting provision: power pursuant to section exercised (19.02.1996) by *Medical Preparations (Licensing of Manufacture) (Amendment) Regulations 1996* (S.I. No. 42 of 1996), in operation as per reg. 5; revoked (23.07.2007) by *Medicinal Products (Control of Manufacture) Regulations 2007* (S.I. No. 539 of 2007), reg. 16, in operation as per reg. 2.

F30[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)*.**]**

Annotations

Amendments:

F30 Inserted (22.07.2007) by *Irish Medicines Board (Miscellaneous Provisions) Act 2006* (3/2006), s. 17, S.I. No. 543 of 2007.

F31**[**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,

F32[(*l*) inspect and copy or extract information from any data, including data that constitutes personal data within the meaning of—

(i) the Data Protection Regulation, or

(ii) Part 5 of the Data Protection Act 2018.**]**

(*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.**]**

F33**[**(12) In this section, "Data Protection Regulation" means Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016[20] on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).**]**

Annotations

Amendments:

F31 Inserted (22.07.2007) by *Irish Medicines Board (Miscellaneous Provisions) Act 2006* (3/2006), s. 17, S.I. No. 543 of 2007.

F32 Substituted (25.05.2018) by *Data Protection Act 2018* (7/2018), s. 182(a), S.I. No. 174 of 2018.

F33 Inserted (25.05.2018) by *Data Protection Act 2018* (7/2018), s. 182(b), S.I. No. 174 of 2018.

F34**[**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—

[20] OJ No. L 119, 4.5.2016, p.1

(*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)*.**]**

Annotations

Amendments:

F34 Inserted (22.07.2007) by *Irish Medicines Board (Miscellaneous Provisions) Act 2006* (3/2006), s. 17, S.I. No. 543 of 2007.

F35**[**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.**]**

Annotations

Amendments:

F35 Inserted (22.07.2007) by *Irish Medicines Board (Miscellaneous Provisions) Act 2006* (3/2006), s. 17, S.I. No. 543 of 2007.

F36**[**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.**]**

Annotations

Amendments:

F36 Inserted (22.07.2007) by *Irish Medicines Board (Miscellaneous Provisions) Act 2006* (3/2006), s. 17, S.I. No. 543 of 2007. A fine of €2,000 translates into a class C fine, not greater than €2,500, as provided (4.01.2011) by *Fines Act 2010* (8/2010), ss. 3, 6(3) and table ref. no. 1, S.I. No. 662 of 2010.

F37**[**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.**]**

Annotations

Amendments:

F37 Inserted (22.07.2007) by *Irish Medicines Board (Miscellaneous Provisions) Act 2006* (3/2006, s. 17, S.I. No. 543 of 2007.

F38**[**Substitution by pharmacists in case of medicinal product shortage.

32G.—(1) Where the Minister, having consulted with the Health Service Executive and the Health Products Regulatory Authority, is of the opinion that—

(*a*) there is a medicinal product shortage,

(*b*) arising from that shortage, there is likely to be a negative impact on the health service or the health needs of patients that cannot be addressed via other mechanisms, and

(*c*) a protocol under this section would assist in addressing the impacts referred to in *paragraph (b)*,

he or she may prepare and issue a protocol to registered pharmacists authorising registered pharmacists to supply such alternative medicinal product or products as are specified in the protocol for the medicinal product that is in short supply under such conditions as are specified in the protocol and without the need for a further prescription.

(2) In the preparation and issuing of a protocol under this section, the Minister shall act in accordance with regulations made under *section 32H* and shall consult

with the bodies referred to in *subsection (1)* in relation to the content of the protocol.

(3) A protocol prepared and issued under this section shall specify—

(*a*) the medicinal product that is in short supply,

(*b*) the substitutable product,

(*c*) the circumstances in which the registered pharmacist may supply the substitutable product,

(*d*) the time period for which the protocol is in place, and

(*e*) such other conditions or information in respect of the supply by a registered pharmacist of the substitutable medicinal product as the Minister considers appropriate.

(4) The Minister may, where appropriate and following consultation with the Health Products Regulatory Authority and the Health Service Executive, amend the time period during which the protocol is in place or any conditions specified in the protocol.

(5) The Minister shall publish or cause to be published each protocol issued (or amended) under this section in such form and manner, including on a website maintained by or on behalf of the Minister, as the Minister considers appropriate.**]**

Annotations

Amendments:

F38 Inserted (1.01.2025) by *Health (Miscellaneous Provisions) Act 2024* (23/2024), s. 10, S.I. No. 753 of 2024.

F39**[**Regulations governing protocol.

32H.—(1) The Minister shall make regulations providing for the issuing and operation of a protocol.

(2) Without prejudice to the generality of *subsection (1)*, such regulations shall include—

(*a*) the procedures for the preparation and review of a protocol including in relation to—

(i) the assessment of the impact of the medicinal product shortage on the provision of a health service and the health needs of patients,

(ii) the assessment of existing mechanisms to address the negative impacts of a medicinal product shortage, including the availability of appropriate alternatives,

(iii) the identification of a substitutable medicinal product and any conditions that should apply in accordance with its supply, and

(iv) the persons who shall be consulted in relation to the preparation and review,

(*b*) the procedure for the notification of a protocol (including any amendment made to the protocol) to registered pharmacists,

(*c*) the procedure for the operation of a protocol, and

(*d*) the requirements in relation to the notification of the supply of a substitutable medicinal product under a protocol to the person who prescribed the medicinal product that is in short supply.**]**

Annotations

Amendments:

F39 Inserted (1.01.2025) by *Health (Miscellaneous Provisions) Act 2024* (23/2024), s. 10, S.I. No. 753 of 2024.

F40[Reporting of information to support the security of supply of medicines.

32I.—(1) The Health Products Regulatory Authority may require a relevant person to provide to the Authority, in such form and manner and within such period as may be prescribed by regulations made by the Minister, such information in relation to medicinal products within the possession or control of the relevant person as the Authority considers necessary for the purpose of the management of the availability of medicinal products in the State, including—

(*a*) the monitoring of the current and future supply of medicinal products, and

(*b*) the identification and management of medicinal product shortages.

(2) A relevant person shall comply with a requirement set out in regulations made under *subsection (1)*.

(3) In this section, "relevant person" means the following persons involved in the manufacture or supply of a medicinal product:

(*a*) the holder of a manufacturer's authorisation granted under Regulation 8 of the Medicinal Products (Control of Manufacture) Regulations 2007 (S.I. No. 539 of 2007);

(*b*) the holder of a marketing authorisation granted in accordance with the Medicinal Products (Control of Placing on the Market) Regulations 2007;

(*c*) the holder of a community marketing authorisation within the meaning of the Medicinal Products (Control of Placing on the Market) Regulations 2007;

(*d*) the holder of a wholesaler's authorisation granted under Regulation 9 of the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (S.I. No. 538 of 2007);

(*e*) a retail pharmacy business within the meaning of the Pharmacy Act 2007;

(*f*) a hospital;

(*g*) such other persons or legal entities, being persons or entities authorised or entitled to supply medicinal products, as may be prescribed in regulations made by the Minister.**]**

Annotations

Amendments:

F40 Inserted (1.01.2025) by *Health (Miscellaneous Provisions) Act 2024* (23/2024), s. 10, S.I. No. 753 of 2024.

Offences by bodies corporate.

33.—(1) Where an offence under this Act has been committed by a body corporate and is proved to have been committed with the consent or connivance of or to be attributable to any neglect on the part of a person being a director, manager, secretary or other officer of the body corporate, or a person who was purporting to act in any such capacity, that person as well as the body corporate shall be guilty of an offence and be liable to be proceeded against and punished as if he or she were guilty of the first-mentioned offence.

(2) Where the affairs of a body corporate are managed by its members, *subsection (1)* shall apply in relation to the acts and defaults of a member in connection with his or her functions of management as if he or she were a director or manager of the body corporate.

Repeal and transitional provisions.

34.—(1) Section 65 of the Health Act, 1947 is hereby repealed.

(2) The National Drugs Advisory Board (Establishment) Order, 1966 (S.I. No. 163 of 1966), is hereby revoked.

(3) A licence granted or renewed under regulations under the said section 65 and in force immediately before the commencement of this section shall continue in force after such commencement as if granted or renewed under regulations under *section 32* and may be revoked or amended accordingly.

(4) Regulations under the said section 65 in force immediately before the commencement of this section shall continue in force after such commencement and may be amended or revoked, as if made under *section 32*.

Annotations

Modifications (not altering text):

C14 Application of Act extended (15.06.2000) by *Customs-Free Airport (Extension of Laws) Regulations 2000* (S.I. No. 169 of 2000), reg. 3.

3. The provisions of the *Irish Medicines Board Act 1995* (No 29 of 1995), together with any Regulations made under Section 32 thereof and any other Regulations in force for the time being by virtue of Section 34(4) of the said Act, are hereby extended to the Customs-free Airport at Shannon.

Editorial Notes:

E171 Power pursuant to section exercised (17.06.1999) by *Medicinal Products (Amendment) Regulations 1999* (S.I. No. 188 of 1999).

Amendment of enactments.

35.—(1) The enactments specified in *column (3)* of the *Schedule* to this Act at any reference number are hereby amended to the extent specified in *column (4)* of that F41**[**Schedule 1**]** at that reference number.

(2) References to the Minister in the Control of Clinical Trials Act, 1987, other than sections 17 and 18, shall, on and after the commencement of this section, be construed as references to the Board.

(3) References to the Minister in the Control of Clinical Trials and Drugs Act, 1990, other than section 5, shall, on and after the commencement of this section, be construed as references to the Board.

Annotations

Amendments:

F41 Substituted (22.07.2007) by *Irish Medicines Board (Miscellaneous Provisions) Act 2006* (3/2006), s. 18, S.I. No. 543 of 2007.

Expenses.

36.—The expenses incurred by the Minister in the administration of this Act shall, to such extent as may be sanctioned by the Minister for Finance, be paid out of moneys provided by the Oireachtas.

Laying of orders and regulations before Houses of Oireachtas.

37.—Every order or regulation made by the Minister under this Act shall be laid before each House of the Oireachtas as soon as may be after it is made and, if a resolution annulling the order or regulation is passed by either such House within the next subsequent 21 days on which that House has sat after the order or regulation is laid before it, the order or regulation shall be annulled accordingly but without prejudice to the validity of anything previously done thereunder.

Short title and commencement.

38.—(1) This Act may be cited as the Irish Medicines Board Act, 1995.

(2) This Act shall come into operation on such day or days as, by order or orders made by the Minister, may be fixed therefor either generally or with reference to any particular purpose or provision and different days may be so fixed for different purposes and different provisions.

Annotations

Editorial Notes:

E172 Power pursuant to subs. exercised (19.02.1996) by *Irish Medicines Board Act 1995 (Commencement) Order 1996* (S.I. No. 40 of 1996).

2. The Irish Medicines Board Act 1995 in so far as is provided for in paragraphs (a), (b) and (e) of subsection 1 of section 4, and section 35 and the schedule to the Act shall come into operation on the 19th day of February, 1996.

E173 Power pursuant to subs. exercised (1.01.1996) by *Irish Medicines Board Act 1995 (Commencement) Order 1995* (S.I. No. 345 of 1995).

2. The Irish Medicines Board Act 1995, except in so far as is provided for in paragraphs (a), (b) and (e) of subsection 1 of section 4, and section 35 and the schedule to the Act, shall come into operation on the 1st day of January, 1996.

Section 35.

F42[SCHEDULE 1]

AMENDMENT OF ENACTMENTS

Reference Number	Number and Year	Short Title	Amendment
(1)	(2)	(3)	(4)
1.	No. 12 of 1961	Poisons Act, 1961	In section 3 (3) (*a*), "*section 32* of the *Irish Medicines Board Act, 1995*" shall be substituted for "section 65 of the Health Act, 1947". In section 3 (3) (*b*), "*section 32*" shall be substituted for "section 65"
2.	No. 28 of 1987	Control of Clinical Trials Act, 1987	In section 2(3)(*b*)(i), "and have not later than 6 weeks after being so notified, made a recommendation to the Minister on the proposal" shall be deleted. In section 2(3)(*b*)(ii), "the Board, not later than 6 weeks after being so notified" shall be substituted for "the Minister". In section 4(1), "after consultation with the National Drugs Advisory Board" shall be deleted. In section 5(1), "after consultation with the National Drugs Advisory Board and" shall be deleted. In section 7, "after consultation with the National Drugs Advisory Board" shall be deleted.
3.	No. 17 of 1990	Control of Clinical Trials and Drugs Act, 1990	In section 5(2), "under Article 4 of the National Drugs Advisory Board (Establishment) Order, 1966" shall be deleted.

Reference Number (1)	Number and Year (2)	Short Title (3)	Amendment (4)
			In section 5(2)(*b*), "a committee or subcommittee established under *section 9* of the *Irish Medicines Board Act, 1995*" shall be substituted for "a committee established under Article 18 of the National Drugs Advisory Board (Establishment) Order, 1966 (S.I. No. 163 of 1966),".

Annotations

Amendments:

F42 Substituted (22.07.2007) by *Irish Medicines Board (Miscellaneous Provisions) Act 2006* (3/2006), s. 19, S.I. No. 543 of 2007.

F43**[**Section 32D.

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].

[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.
* Delete whichever is inapplicable.
[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.
* Delete whichever is inapplicable.
[5] Here insert the relevant results as appropriate.

Signature

Date

Address**]**

Annotations

Amendments:

F43 Inserted (22.07.2007) by *Irish Medicines Board (Miscellaneous Provisions) Act 2006* (3/2006), s. 20, S.I. No. 543 of 2007.

ACTS REFERRED TO

Civil Service Regulation Act, 1956	1956, No. 46
Control of Clinical Trials Act, 1987	1987, No. 28
Control of Clinical Trials Acts, 1987 and 1990	
Control of Clinical Trials and Drugs Act, 1990	1990, No. 17
European Assembly Elections Act, 1977	1977, No. 16
European Parliament Elections Act, 1993	1993, No. 30
Finance Act, 1895	1895, c. 16
Health Act, 1947	1947, No. 28
Health (Corporate Bodies) Act, 1961	1961, No. 27
Holidays (Employees) Acts, 1973 and 1991	
Local Government Superannuation Act, 1980	1980, No. 8
Minimum Notice and Terms of Employment Acts, 1973 to 1991	
Petty Sessions (Ireland) Act, 1851	1851, c. 93
Poisons Act, 1961	1961, No. 12
Public Offices Fees Act, 1879	1879, c. 58
Redundancy Payments Acts, 1967 to 1991	
Terms of Employment (Information) Act, 1994	1994, No. 5
Unfair Dismissals Acts, 1977 to 1993	

Number 29 *of* 1995

IRISH MEDICINES BOARD ACT 1995

REVISED

Updated to 30 June 2026

About this Revised Act

This Revised Act presents the text of the Act as it has been amended since enactment, and preserves the format in which it was passed.

Related legislation

Irish Medicines Board Acts 1995 and 2006: this Act is one of a group of Acts included in this collective citation, to be construed together as one (*Irish Medicines Board (Miscellaneous Provisions) Act 2006*, s. 1(3)). The Acts in the group are:

- *Irish Medicines Board Act 1995* (29/1995)
- *Irish Medicines Board (Miscellaneous Provisions) Act 2006* (3/2006), Part 3 (ss. 10-20)

Annotations

This Revised Act is annotated and includes textual and non-textual amendments, statutory instruments made pursuant to the Act and previous affecting provisions.

An explanation of how to read annotations is available at www.lawreform.ie/annotations.

Material not updated in this revision

Where other legislation is amended by this Act, those amendments may have been superseded by other amendments in other legislation, or the amended legislation may have been repealed or revoked. This information is not represented in this revision but will be reflected in a revision of the amended legislation if one is available.

Where legislation or a fragment of legislation is referred to in annotations, changes to this legislation or fragment may not be reflected in this revision but will be reflected in a revision of the legislation referred to if one is available.

A list of legislative changes to any Act, and to statutory instruments from 1972, may be found linked from the page of the Act or statutory instrument at www.irishstatutebook.ie.

Acts which affect or previously affected this revision

- *Health (Miscellaneous Provisions) Act 2024* (23/2024)
- *Data Protection Act 2018* (7/2018)
- *Health (Miscellaneous Provisions) Act 2017* (1/2017)
- *Freedom of Information Act 2014* (30/2014)

- *Health (Pricing and Supply of Medical Goods) Act 2013* (14/2013)
- *Ministers and Secretaries (Amendment) Act 2011* (10/2011)
- *Fines Act 2010* (8/2010)
- *Irish Medicines Board (Miscellaneous Provisions) Act 2006* (3/2006)
- *Health Act 2004* (42/2004)
- *Finance Act 1999* (2/1999)
- *Freedom of Information Act 1997* (13/1997)

All Acts up to and including *Critical Infrastructure Act 2026* (16/2026), enacted 25 June 2026, were considered in the preparation of this revision.

Statutory instruments which affect or previously affected this revision

- *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2026* (S.I. No. 138 of 2026)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2025* (S.I. No. 625 of 2025)
- *Health Products Regulatory Authority (Fees) Regulations 2025* (S.I. No. 624 of 2025)
- *Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2025* (S.I. No. 504 of 2025)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 3) Regulations 2025* (S.I. No. 503 of 2025)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2025* (S.I. No. 418 of 2025)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2025* (S.I. No. 353 of 2025)
- *Health Products Regulatory Authority (Fees) Regulations 2024* (S.I. No. 751 of 2024)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 5) Regulations 2024* (S.I. No. 582 of 2024)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2024* (S.I. No. 458 of 2024)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 3) Regulations 2024* (S.I. No. 162 of 2024)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2024* (S.I. No. 73 of 2024)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2024* (S.I. No. 72 of 2024)
- *Health Products Regulatory Authority (Fees) Regulations 2023* (S.I. No. 697 of 2023)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2023* (S.I. No. 584 of 2023)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 6) Regulations 2023* (S.I. No. 451 of 2023)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 5) Regulations 2023* (S.I. No. 422 of 2023)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2023* (S.I. No. 284 of 2023)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 3) Regulations 2023* (S.I. No. 238 of 2023)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2023* (S.I. No. 105 of 2023)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2023* (S.I. No. 11 of 2023)
- *Health Products Regulatory Authority (Fees) Regulations 2022* (S.I. No. 679 of 2022)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 5) Regulations 2022* (S.I. No. 467 of 2022)
- *Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2022* (S.I. No. 416 of 2022)
- *Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2022* (S.I. No. 415 of 2022)
- *Medicinal Products (Control of Manufacture) (Amendment) (No. 2) Regulations 2022* (S.I. No. 414 of 2022)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2022* (S.I. No. 402 of 2022)
- *In Vitro Diagnostic Medical Devices (Registration) Regulations 2022* (S.I. No. 365 of 2022)
- *Medicinal Products (Safety Features on Packaging) Regulations 2022* (S.I. No. 270 of 2022)
- *In Vitro Diagnostic Medical Devices Regulations 2022* (S.I. No. 256 of 2022)

- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 3) Regulations 2022* (S.I. No. 84 of 2022)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2022* (S.I. No. 57 of 2022)
- *Medicinal Products (Control of Manufacture) (Amendment) Regulations 2022* (S.I. No. 43 of 2022)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2022* (S.I. No. 32 of 2022)
- *Health Products Regulatory Authority (Fees) Regulations 2021* (S.I. No. 744 of 2021)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 15) Regulations 2021* (S.I. No. 718 of 2021)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 14) Regulations 2021* (S.I. No. 692 of 2021)
- *Medical Devices (Registration) Regulations 2021* (S.I. No. 691 of 2021)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 13) Regulations 2021* (S.I. No. 605 of 2021)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 12) Regulations 2021* (S.I. No. 578 of 2021)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 11) Regulations 2021* (S.I. No. 558 of 2021)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 10) Regulations 2021* (S.I. No. 511 of 2021)
- *Medical Devices (Amendment) Regulations 2021* (S.I. No. 510 of 2021)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 9) Regulations 2021* (S.I. No. 492 of 2021)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) No. 8 Regulations 2021* (S.I. No. 411 of 2021)
- *Medical Devices Regulations 2021* (S.I. No. 261 of 2021)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2021* (S.I. No. 245 of 2021)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 6) Regulations 2021* (S.I. No. 155 of 2021)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 5) Regulations 2021* (S.I. No. 130 of 2021)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2021* (S.I. No. 81 of 2021)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 3) Regulations 2021* (S.I. No. 43 of 2021)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2021* (S.I. No. 8 of 2021)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2021* (S.I. No. 2 of 2021)
- *Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2021* (S.I. No. 1 of 2021)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020* (S.I. No. 698 of 2020)
- *Health Products Regulatory Authority (Fees) Regulations 2020* (S.I. No. 654 of 2020)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 6) Regulations 2020* (S.I. No. 614 of 2020)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 5) Regulations 2020* (S.I. No. 401 of 2020)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 4) Regulations 2020* (S.I. No. 241 of 2020)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 3) Regulations 2020* (S.I. No. 204 of 2020)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2020* (S.I. No. 177 of 2020)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2020* (S.I. No. 98 of 2020)
- *Health Products Regulatory Authority (Fees) Regulations 2019* (S.I. No. 700 of 2019)
- *Medicinal Products (Control of Manufacture) (Amendment) Regulations 2019* (S.I. No. 219 of 2019)
- *Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2019* (S.I. No. 218 of 2019)
- *Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2019* (S.I. No. 217 of 2019)
- *Medicinal Products (Safety Features On Packaging) Regulations 2019* (S.I. No. 36 of 2019)

- *Health Products Regulatory Authority (Fees) (No. 2) Regulations 2018* (S.I. No. 531 of 2018)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2018* (S.I. No. 530 of 2018)
- *Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2018* (S.I. No. 529 of 2018)
- *Health Products Regulatory Authority (Fees) Regulations 2018* (S.I. No. 208 of 2018)
- *Health Products Regulatory Authority (Fees) Regulations 2017* (S.I. No. 557 of 2017)
- *European Union (Medical Devices and In Vitro Diagnostic Medical Devices) Regulations 2017* (S.I. No. 547 of 2017)
- *Health Products Regulatory Authority (Fees) Regulations 2016* (S.I. No. 602 of 2016)
- *Health Products Regulatory Authority (Fees) Regulations 2015* (S.I. No. 599 of 2015)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2015* (S.I. No. 449 of 2015)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2015* (S.I. No. 87 of 2015)
- *Health Products Regulatory Authority (Fees) Regulations 2014* (S.I. No. 607 of 2014)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 2) Regulations 2014* (S.I. No. 504 of 2014)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2014* (S.I. No. 300 of 2014)
- *Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2014* (S.I. No. 151 of 2014)
- *Irish Medicines Board (Fees) Regulations 2013* (S.I. No. 510 of 2013)
- *Irish Medicines Board (Fees) (Amendment) Regulations 2013* (S.I. No. 165 of 2013)
- *Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2013* (S.I. No. 164 of 2013)
- *Medicinal Products (Control of Manufacture) (Amendment) Regulations 2013* (S.I. No. 163 of 2013)
- *Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2013* (S.I. No. 162 of 2013)
- *Irish Medicines Board (Fees) Regulations 2012* (S.I. No. 572 of 2012)
- *Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2012* (S.I. No. 274 of 2012)
- *Medicinal Products (Control of Manufacture) (Amendment) Regulations 2012* (S.I. No. 273 of 2012)
- *Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2012* (S.I. No. 272 of 2012)
- *European Communities (In Vitro Diagnostic Medical Devices) (Amendment) Regulations 2012* (S.I. No. 207 of 2012)
- *Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2011* (S.I. No. 722 of 2011)
- *Irish Medicines Board (Fees) Regulations 2011* (S.I. No. 684 of 2011)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2011* (S.I. No. 525 of 2011)
- *Finance (Transfer of Departmental Administration and Ministerial Functions) Order 2011* (S.I. No. 418 of 2011)
- *Irish Medicines Board (Fees) Regulations 2010* (S.I. No. 632 of 2010)
- *Medicinal Products (Control of Manufacture) Regulations 2007 (Amendment) Regulations 2010* (S.I. No. 288 of 2010)
- *Medicinal Products (Control of Placing on the Market) Regulations 2007 (Amendment) Regulations 2010* (S.I. No. 287 of 2010)
- *Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (Amendment) Regulations 2010* (S.I. No. 286 of 2010)
- *Medicinal Products (Control of Placing On the Market) Regulations 2007 (Amendment) (No. 2) Regulations 2009* (S.I. No. 553 of 2009)
- *Irish Medicines Board (Fees) Regulations 2009* (S.I. No. 551 of 2009)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2009* (S.I. No. 442 of 2009)
- *Medicinal Products (Control of Manufacture) Regulations 2007 (Amendment) Regulations 2009* (S.I. No. 4 of 2009)
- *Medicinal Products (Control of Placing On the Market) Regulations 2007 (Amendment) Regulations 2009* (S.I. No. 3 of 2009)
- *Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (Amendment) Regulations 2009* (S.I. No. 2 of 2009)
- *Irish Medicines Board (Fees) Regulations 2008* (S.I. No. 542 of 2008)

- *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2008* (S.I. No. 512 of 2008)
- *Irish Medicines Board (Fees) Regulations 2007* (S.I. No. 866 of 2007)
- *European Communities (Amendment of the Irish Medicines Board Act 1995) Regulations 2007* (S.I. No. 542 of 2007)
- *Medicinal Products (Control of Advertising) Regulations 2007* (S.I. No. 541 of 2007)
- *Medicinal Products (Control of Placing on the Market) Regulations 2007* (S.I. No. 540 of 2007)
- *Medicinal Products (Control of Manufacture) Regulations 2007* (S.I. No. 539 of 2007)
- *Medicinal Products (Control of Wholesale Distribution) Regulations 2007* (S.I. No. 538 of 2007)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2007* (S.I. No. 201 of 2007)
- *Medicinal Products (Revocation of the Medical Preparations (Control of Amphetamine) Regulations 1969) Regulations 2007* (S.I. No. 99 of 2007)
- *Irish Medicines Board (Fees) Regulations 2006* (S.I. No. 617 of 2006)
- *Irish Medicines Board (Fees) Regulations 2005* (S.I. No. 882 of 2005)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2005* (S.I. No. 510 of 2005)
- *Irish Medicines Board (Fees) Regulations 2004* (S.I. No. 877 of 2004)
- *Medicinal Products (Amendment) Regulations 2004* (S.I. No. 663 of 2004)
- *Irish Medicines Board (Fees) (Amendment) Regulations 2004* (S.I. No. 524 of 2004)
- *Irish Medicines Board (Fees) Regulations 2003* (S.I. No. 731 of 2003)
- *Medicinal Products (Prescription and Control of Supply) Regulations 2003* (S.I. No. 540 of 2003)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2002* (S.I. No. 627 of 2002)
- *European Communities (Medical Devices) (Amendment) Regulations 2002* (S.I. No. 576 of 2002)
- *Irish Medicines Board (Fees) (Medicinal Products For Human Use) Regulations 2002* (S.I. No. 262 of 2002)
- *Medicinal Products (Licensing and Sale) (Amendment) Regulations 2001* (S.I. No. 512 of 2001)
- *European Communities (Medical Devices) (Amendment) Regulations 2001* (S.I. No. 444 of 2001)
- *European Communities (In Vitro Diagnostic Medical Devices) Regulations 2001* (S.I. No. 304 of 2001)
- *Medicinal Products (Control of Paracetamol) Regulations 2001* (S.I. No. 150 of 2001)
- *Irish Medicines Board (Fees) (Amendment) Regulations 2000* (S.I. No. 233 of 2000)
- *Customs-Free Airport (Extension of Laws) Regulations 2000* (S.I. No. 169 of 2000)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2000* (S.I. No. 116 of 2000)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 1999* (S.I. No. 271 of 1999)
- *Medicinal Products (Amendment) Regulations 1999* (S.I. No. 188 of 1999)
- *Medical Preparations (Labelling and Package Leaflets) (Amendment) Regulations 1999* (S.I. No. 187 of 1999)
- *Irish Medicines Board (Competent Authority) Order 1998* (S.I. No. 143 of 1998)
- *Medicinal Products (Licensing and Sale) Regulations 1998* (S.I. No. 142 of 1998)
- *Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 1996* (S.I. No. 309 of 1996)
- *Medical Preparations (Advertising) (Amendment) Regulations 1996* (S.I. No. 308 of 1996)
- *Medicinal Products (Prescription and Control of Supply) Regulations 1996* (S.I. No. 256 of 1996)
- *Irish Medicines Board (Fees) Regulations 1996* (S.I. No. 44 of 1996)
- *Medical Preparations (Licensing and Sale) Regulations 1996* (S.I. No. 43 of 1996)
- *Medical Preparations (Licensing of Manufacture) (Amendment) Regulations 1996* (S.I. No. 42 of 1996)
- *Medical Preparations (Wholesale Licences) (Amendment) Regulations 1996* (S.I. No. 41 of 1996)
- *Irish Medicines Board Act 1995 (Commencement) Order 1996* (S.I. No. 40 of 1996)
- *Irish Medicines Board Act 1995 (Establishment) Order 1995* (S.I. No. 346 of 1995)
- *Irish Medicines Board Act 1995 (Commencement) Order 1995* (S.I. No. 345 of 1995)

All statutory instruments up to and including *Statistics (Structural Business Inquiry) (Amendment) Order 2026* (S.I. No. 311 of 2026), made 30 June 2026, were considered in the preparation of this revision.