

# Irish Medicines Board Act, 1995



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*Number 29 of 1995*

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## **IRISH MEDICINES BOARD ACT, 1995**

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### ARRANGEMENT OF SECTIONS

#### Section

1. [Interpretation.](#)
2. [Establishment day.](#)
3. [Establishment of Irish Medicines Board.](#)
4. [Functions of Board.](#)
5. [Conferral of additional functions on Board.](#)
6. [Chairperson of Board.](#)
7. [Members of Board.](#)
8. [Meetings of Board.](#)
9. [Advisory committees.](#)
10. [Chief Executive.](#)
11. [Staff of Board.](#)
12. [Superannuation of staff of Board.](#)
13. [Fees.](#)
14. [Charges for services.](#)
15. [Grants to Board.](#)
16. [Gifts.](#)
17. [Borrowing by Board.](#)
18. [Accounts and audits of Board.](#)

- [19. Reports and information to Minister.](#)
- [20. Assessment by Board of performance of certain of its functions.](#)
- [21. General duty of Board.](#)
- [22. Membership of either House of Oireachtas or of European Parliament.](#)
- [23. Disclosure of information.](#)
- [24. Disclosure of interests.](#)
- [25. Dissolution of former Board.](#)
- [26. Transfer of assets and liabilities of former Board.](#)
- [27. Preservation of certain continuing contracts and adaptation of references to former Board.](#)
- [28. Saving for certain acts.](#)
- [29. Pending legal proceedings.](#)
- [30. Exemption from stamp duty.](#)
- [31. Completion of certain matters commenced by Minister or by former Board.](#)
- [32. Regulations.](#)
- [33. Offences by bodies corporate.](#)
- [34. Repeal and transitional provisions.](#)
- [35. Amendment of enactments.](#)
- [36. Expenses.](#)
- [37. Laying of orders and regulations before Houses of Oireachtas.](#)
- [38. Short title and commencement.](#)

## SCHEDULE

Amendment of Enactments



**IRISH MEDICINES BOARD ACT, 1995**

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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. [15th November, 1995]

BE IT ENACTED BY THE OIREACHTAS AS FOLLOWS:

Interpretation.

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

“*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) ;

“*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;

“*medicinal product*” has the meaning assigned to it by Council Directive No. 65/65/EEC of 26 January 1965(2) ;

“*the Minister*” means the Minister for Health;

“*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 Board.

(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.

Establishment day.

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

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.

Functions of Board.

**4.**—(1) The principal functions of the Board shall be—

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

(b) subject to *subsection (4)*, to exercise the powers conferred on the competent authority by Council Directive No. 65/65/EEC of 26 January 1965, as amended, and any regulations under the [Health Act, 1947](#), giving effect to that Directive as amended,

- (c) to exercise the powers conferred on the supervisory authority by Council Regulation (EEC) No. 2309/93 of 22 July 1993(3) ,
- (d) to exercise the powers conferred on the competent authority by Council Directive No. 81/851/EEC of 28 September 1981(4) ,
- (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,
- (k) to furnish, whenever it is so requested by the Minister, advice to the Minister in relation to the certification for export or any other purpose of medicinal products manufactured in the State,
- (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.

(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.

(4) Upon such day as the Minister may by order appoint, the Board shall be the competent authority for the purposes of Council Directive No. 65/65/EEC of 26 January 1965, as amended, and for the purposes of any regulations under the [Health Act, 1947](#), giving effect to that Directive, as amended, and the Minister shall cease to be such authority.

(5) In this section “*medical device*” means an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which—

(a) is intended by the manufacturer to be used in relation to human beings for the purpose of—

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease,

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

(iii) investigation, replacement or modification of the anatomy or of a physiological process, or

(iv) control of conception;

and

(b) does not achieve its principal intended action in or on the human body by pharmacological, immunological or

metabolic means, even if it is assisted in its function by such means.

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) 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).

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) The chairperson of the Board shall be paid such remuneration (if any) and such allowances for expenses as the Minister, with the consent of the Minister for Finance, may from time to time

determine.

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.

(9) Of the members of the Board—

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

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

but the same member shall not be the chairperson of both such committees.

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) A person (other than the chairperson) shall not receive any remuneration for acting as a member of the Board, but may be paid such travelling and subsistence allowances as are approved of by the Minister with the consent of the Minister for Finance.

(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.

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)*.

(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.

(8) The Board shall not refuse to grant a licence in respect of a medicinal product on any ground relating to the safety, quality, or efficacy of a medicinal product unless it has requested the advice of the appropriate committee in relation thereto and considered such advice.

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

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.**—(1) The Minister may make regulations providing for the payment to the Board of fees in relation to the grant or renewal of licences by the Board under [section 32](#) and the regulations may provide for different fees or for exemption from the payment of fees or for the waiver, remission or refund (in whole or in part) of fees 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 application or matter, the application or matter 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.

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.

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.

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.

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.

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.**—Section 12 of the Finance Act, 1895, shall not apply to the vesting in the Board of any property or rights transferred by this Act.

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 or cosmetic products, make provision for—

- (a) the regulation (including the control) of the manufacture, production, preparation, importation, distribution, sale, supply, placing on the market, advertisement or promotion of the product or products 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 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),
- (c) the prohibition of the advertisement of the product or products to which the regulations relate either absolutely or subject to specified conditions (including the grant by the Board of a licence for the advertisement of such

products) and the prohibition of the sale or offering or keeping for sale of any such product which is advertised in contravention of such regulations,

- (d) the regulation and control of the packaging and labelling of the product or products to which the regulations relate and, in particular, for the specification of information relating to such product or products to be contained on any packet used in the sale, supply or distribution of such product or products or on a label attached to such packet,
- (e) the determination of the classes of persons to whom licences under the regulations are to be granted,
- (f) the specification of conditions for the grant, suspension, retention, amendment or renewal of licences under the regulations,
- (g) the refusal or revocation of licences under the regulations,
- (h) the requiring of applicants for or holders of licences under the regulations to furnish specified information in regard to the constitution, manufacture, importation, storage, distribution, sale or advertisement of the product or products to which their applications or licences relate,
- (i) the enforcement and execution of the regulations by and the conferral of such powers as the Minister considers appropriate for the purpose of such enforcement and execution on the following persons—
  - (i) officers of the Minister,
  - (ii) officers of the Board,
  - (iii) health boards and their officers,
  - (iv) with the consent of the Minister for Finance, officers of Customs and Excise,
  - (v) with the consent of the Minister for Enterprise and Employment, officers of that Minister, and
  - (vi) officers of the Pharmaceutical Society of Ireland,
- (j) the giving and taking (without payment) of samples of the product or products to which the regulations relate and the carrying out of tests, examinations and analyses of such samples,

- (k) the determination of the classes of persons to be responsible for the carrying out of tests, examinations and analyses of samples of the product or products to which the regulations relate and the means by and the manner in which such test, examination or analysis is to be made,
- (l) the prescribing of the certificate or other evidence to be given of the result of any test, examination or analysis and the classes of persons by and to whom such certificate or evidence is to be given,
- (m) any certificate or other evidence prescribed under *paragraph (1)* of this subsection and given in respect of the test, examination or analysis of a sample shall, as respects that sample, be evidence for all purposes of the result of such test.

(3) Any regulation made by the Minister under this Act may contain such incidental or consequential provisions as appear to the Minister to be necessary or expedient for the purpose of implementing the provisions 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 £1,500 or to imprisonment for a term not exceeding one year, or to both,

(b) on conviction on indictment—

(i) in the case of a first offence, to a fine not exceeding £100,000 or to imprisonment for a term not exceeding 10 years or to both,

(ii) in the case of a second or subsequent offence to a fine not exceeding £250,000, or to imprisonment for a term not exceeding 10 years or to 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.

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](#).

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 Schedule 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.

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.

## SCHEDULE

### Amendment of Enactments

#### Section 35.

Reference Number	Number and Year	Short Title	Amendment
(1)	(2)	(3)	(4)
1.	No. 12 of 1961	<u>Poisons Act, 1961</u>	In <u>section 3</u> (3) (a), “ <u>section 32</u> of the <i>Irish Medicines Board Act, 1995</i> ” shall be substituted for “ <u>section 65</u> of the <u>Health Act, 1947</u> ”.
			In <u>section 3</u> (3) (b), “ <u>section 32</u> ” shall be substituted for “section 65”
2.	No. 28 of 1987	<u>Control of Clinical Trials Act, 1987</u>	In <u>section 2</u> (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 <u>section 2</u> (3)(b)(ii), “the Board, not later than 6 weeks after being so notified” shall be substituted for “the Minister”.
			In <u>section 4</u> (1), “after consultation with the National Drugs Advisory Board” shall be deleted.
			In <u>section 5</u> (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.

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),”.

Acts Referred to

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

<sup>(1)</sup> OJ. No. L151, 23.6.93, p.32

<sup>(2)</sup> O.J. No. 22, 9.2.65, p.369/65

<sup>(3)</sup> O.J. No. L214, 28.4.93, p.1

<sup>(4)</sup> OJ. No. L317, 6.11.81, p.1