



# **DÁIL ÉIREANN**

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## **AN BILLE CÓGAISÍOCHTA 2007 PHARMACY BILL 2007**

### **LEASUITHE COISTE COMMITTEE AMENDMENTS**

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# DÁIL ÉIREANN

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## AN BILLE CÓGAISÍOCHTA 2007 —ROGHCHOISTE

### PHARMACY BILL 2007 —SELECT COMMITTEE

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#### *Leasuithe Amendments*

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#### SECTION 2

1. In page 8, subsection (1), line 22, after “*section 13*” to insert the following:

“and “registered” and connected expressions shall be construed accordingly”.

—An tAire Sláinte agus Leanaí.

#### SECTION 5

2. In page 9, lines 17 to 19, to delete subsection (1) and substitute the following:

“5.—(1) Notwithstanding the repeal by section 4 of the Pharmacy (Ireland) Act 1875, the Pharmaceutical Society of Ireland shall continue in being subject to and as reconstituted by this Act.”.

—Liz McManus.

3. In page 9, subsection (2), line 20, after “as” to insert the following:

“Cumann Cógaiseoirí na hÉireann, or, in the English language,”.

—An tAire Sláinte agus Leanaí, Liz McManus.

#### SECTION 7

4. In page 12, between lines 4 and 5, to insert the following subsection:

“(3) Without prejudice to the generality of *subsection (2)(a)(ii)*, the Society’s duty under that provision shall include determining and applying criteria for registration which require compliance with any codes of conduct drawn up for pharmacists and undertakings to comply with such codes.”.

—Liz McManus, Liam Twomey.

5. In page 12, between lines 4 and 5, to insert the following subsection:

“(3) Without prejudice to the generality of *subsection (2)(a)(iii)*, the Society’s duty under that provision shall include the drawing up of codes of conduct for pharmacists which make detailed provision for conflicts of interest, and, without limitation, for such conflicts as might arise as a result of certain relationships and arrangements between pharmacists and medical practitioners, or persons connected with them (including those relating to the letting of premises), and which require certain declarations and disclosures to be made in that regard.”.

—Liz McManus.

6. In page 12, between lines 4 and 5, to insert the following subsection:

[ SECTION 7 ]

“(3) Without prejudice to the generality of *subsection (2)(a)(iii)*, the Society’s duty under that provision shall include the drawing up of codes of conduct for pharmacists which make detailed provision for conflicts of interest and which require certain declarations and disclosures to be made in that regard.”.

—Liam Twomey.

SECTION 10

7. In page 12, subsection (2), lines 26 and 27, to delete “by the Minister” and substitute “or elected as set out in *subsection (3)*”.

—Liz McManus.

8. In page 13, subsection (3)(f), line 14, after “members” to insert the following:

“in accordance with regulations regarding election of those members prescribed by the Society, or, in the case of the first such election, by the Minister”.

—Liz McManus.

9. In page 13, subsection (3)(g)(i), line 20, to delete “pharmacy faculties” and substitute “schools of pharmacy”.

—An tAire Sláinte agus Leanaí.

10. In page 13, to delete lines 26 to 30 and substitute the following:

“(4) In—

(a) making nominations under *subsection (3)(a)* and (b), the bodies there referred to, and

(b) making appointments in pursuance of *subsection (3)(c)*, (d) and (e), the Minister,”.

—An tAire Sláinte agus Leanaí.

11. In page 13, between lines 33 and 34, to insert the following subsection:

“(5) In relation to the first Council appointed after the establishment of the Society, the 9 persons referred to in *subsection (3)(f)* shall be members of the Council of the old Society selected for the purposes of this section by the members of the Council of the old Society before its dissolution.”.

—An tAire Sláinte agus Leanaí.

12. In page 13, between lines 35 and 36, to insert the following subsection:

“(6) Not less than 40 per cent of the members of a Body shall be men and not less than 40 per cent shall be women.”.

—Liz McManus.

SECTION 12

13. In page 14, subsection (1), between lines 23 and 24, to insert the following:

“(a) before drafting or giving effect to a code of conduct, consult with bodies which are representative of the pharmacy sector, and with any other person or body the Council considers appropriate,”.

—Liz McManus.

14. In page 14, subsection (1), between lines 23 and 24, to insert the following:

[ SECTION 12 ]

“(a) consult with any person or body which are representative of the pharmacy sector, and with any other person or body the Council considers appropriate.”.

—Liam Twomey.

SECTION 16

**15.** In page 18, subsection (5), line 36, after “state” where it secondly occurs to insert the following:

“and certified by that state and the person has 3 years professional experience in that state in accordance with Article 3(3) of the Professional Qualifications Directive”.

—Liz McManus.

SECTION 18

**16.** In page 20, subsection (1), line 29, to delete “may” and substitute “shall”.

—Liz McManus, Paudge Connolly.

**17.** In page 21, between lines 28 and 29, to insert the following subsection:

“(2) The Minister shall, prior to making any regulations, consult with bodies which are representative of the pharmacy sector, and with any other person or body the Minister considers appropriate.”.

—Liz McManus, Liam Twomey.

SECTION 24

**18.** In page 23, subsection (1), line 33, to delete “pharmacy faculties” and substitute “schools of pharmacy”.

—An tAire Sláinte agus Leanaí.

SECTION 25

**19.** In page 24, before section 25, but in Part 5, to insert the following new section:

“Encouraging infringement of a code of conduct.

25.—Any person who knowingly helps or, by encouragement, advice or consent, or by an authorisation or order, leads any person to contravene any provision of any code of conduct drawn up by the Society under *section 7(2)(iii)* shall be guilty of an offence.”.

—Liz McManus.

**20.** In page 24, before section 25, but in Part 5, to insert the following new section:

“False declaration.

25.—It shall be an offence for any person knowingly or recklessly to make any declaration or disclosure to the Society which is false, misleading or incomplete.”.

—Liz McManus.

**21.** In page 24, before section 25, but in Part 5, to insert the following new section:

[ SECTION 25 ]

“Prohibition of certain arrangements.

25.—(1) It shall be an offence for any person carrying on a retail pharmacy business, or any partner, connected relative or connected person, servant or agent of such person, to rent or purchase from a medical practitioner, partner, connected relative, or connected person of such practitioner, or otherwise obtain an interest from such persons in, a premises at which such business is, or is intended to be, carried out—

- (a) at a rent, or for other direct or indirect consideration in money or money’s worth, or both, which is not normal for the area in which the premises are located, and
- (b) in circumstances in which the amount of the rent or other consideration, or both, is or are related, directly or indirectly, to the value or volume of business expected to be carried out in the premises (or both) as a consequence of patients of such practitioner purchasing or obtaining medicinal products prescribed by him or her from such pharmacist or pharmacy by reason of its location in the premises concerned.

(2) For the purposes of this section, “connected relative” shall have the meaning assigned to it in *paragraph 9 of Schedule 1* to this Act, and “connected person” shall have the meaning assigned to it in section 2(a) of the Ethics in Public Office Acts 1995 and 2001.”.

—Liz McManus.

22. In page 24, before section 25, to insert the following new section:

“Conflicts of interest.

25.—(1) It shall be an offence for any person carrying on a retail pharmacy business, or any partner, connected relative or connected person, servant or agent of such person—

- (a) directly or indirectly to make, offer or provide to any medical practitioner or any partner, connected relative or connected person of such practitioner, any payment, inducement, consideration in money or money’s worth or financial or other benefit of any kind, in consideration of, or by way of reward for, or in any way relating to—
  - (i) the value or volume (or both) of medicinal products prescribed by that medical practitioner, or
  - (ii) the direct or indirect direction, encouragement or referral by that medical practitioner of his patients to purchase or obtain medicinal products prescribed by him or her from such pharmacist or pharmacy,or both,
- (b) to enter into, or be party to, any agreement, arrangement or understanding, under which, directly or indirectly, any payment, inducement, consideration in money or money’s worth or financial or other benefit of any kind, is made, offered or provided to any medical practitioner or any partner, connected relative or connected person of such practitioner, in consideration of, or by way of reward for, or in any way relating to—
  - (i) the value or volume (or both) of medicinal products prescribed by that medical practitioner, or

[ SECTION 25 ]

(ii) the direct or indirect direction, encouragement or referral by that medical practitioner of his patients to purchase or obtain medicinal products prescribed by him or her from such pharmacist or pharmacy, or both,

(c) directly or indirectly to make, offer or provide to any medical practitioner or any partner, connected relative or connected person of such practitioner, any payment, inducement, consideration in money or money's worth or financial or other benefit of any kind, or to enter into, or be party to, any agreement, arrangement or understanding, under which, directly or indirectly, any such payment, inducement, consideration in money or money's worth or financial or other benefit of any kind, is to be made, offered or provided to any medical practitioner, partner, connected relative, or connected person of such practitioner, the direct, or indirect consequence or effect of which would, or could, be to

(i) increase the value or volume (or both) of medicinal products prescribed by that medical practitioner, or

(ii) cause the direction, encouragement or referral by that medical practitioner of his patients to purchase or obtain medicinal products prescribed by him or her from such pharmacist or pharmacy,

or both.

(2) For the purposes of this section, "connected relative" shall have the meaning assigned to it in *paragraph 9 of Schedule 1* to this Act, and "connected person" shall have the meaning assigned to it in section 2(a) of the Ethics in Public Office Acts 1995 and 2001.

(3) For the purposes of this section, references to any payment, inducement, consideration in money or money's worth or financial or other benefit of any kind, shall include a reference to rent and other consideration in money or money's worth relating to the making available of premises to a person carrying on a retail pharmacy business, and references in this section to any agreement, arrangement or understanding shall include a reference to any agreement, arrangement or understanding (including a lease of premises) by means of which such premises is made available."

—Liz McManus.

**23.** In page 24, before section 25, but in Part 5, to insert the following new section:

"Prohibition of certain arrangements regarding premises.

25.—(1) It shall be an offence for any person carrying on a retail pharmacy business, or any partner, connected relative or connected person, servant or agent of such person, to suffer the location of the premises at which such business is, or intended to be, carried on, to be a premises in which any medical practitioner, or partner of such practitioner, carries on a medical practice, and which premises is under such amount in square metres as may be prescribed, in size and does not contain any units in which any business other than a medical, dental, veterinary, or other similar healthcare-related practice is carried on.

[ SECTION 25 ]

(2) For the purposes of this section, “connected relative” shall have the meaning assigned to it in *paragraph 9 of Schedule 1* to this Act, and “connected person” shall have the meaning assigned to it in section 2(a) of the Ethics in Public Office Acts 1995 and 2001.”

—Liz McManus.

24. In page 24, subsection (2)(a)(i), line 9, after “business” to insert the following:

“or in a business corresponding to a retail pharmacy business”.

—Liz McManus, Paudge Connolly.

25. In page 24, after line 41, to insert the following subsection:

“(3) Any person who knowingly or recklessly makes any declaration or disclosure to the Society which is false, misleading or incomplete is guilty of an offence.”

—Liz McManus.

SECTION 26

26. In page 25, subsection (1)(a), line 4, after “person” to insert “being a registered pharmacist”.

—Liz McManus.

27. In page 25, subsection (1)(a), line 5, after “partnership” to insert “of registered pharmacists”.

—Liz McManus.

28. In page 25, subsection (1)(b), line 6, after “body,” to insert the following:

“or by an unincorporated body wholly or mainly maintained by—

(i) a public body out of public funds,

(ii) a charity, or

(iii) voluntary subscriptions.”

—An tAire Sláinte agus Leanaí.

29. In page 25, subsection (2), line 12, after “than” to insert the following:

“in the course of operating a hospital pharmacy department or”.

—Liz McManus.

30. In page 25, between lines 12 and 13, to insert the following subsection:

“(3) Any person who knowingly helps or, by encouragement, advice or consent, or by an authorisation or order, leads any person to contravene any provision of any code of conduct drawn up by the Society under *section 7(2)(iii)* shall be guilty of an offence.”

—Liz McManus, Liam Twomey.

31. In page 25, between lines 12 and 13, to insert the following subsection:

“(3) Any person who knowingly or recklessly makes any declaration or disclosure to the Society which is false, misleading or incomplete is guilty of an offence.”

—Liam Twomey.

[ SECTION 28 ]

SECTION 28

- 32.** In page 26, paragraph (a)(ii), line 1, after “pharmacist” to insert “and a director or company secretary”.

—Liz McManus.

SECTION 31

- 33.** In page 27, subsection (4), line 28, to delete “judgement” and substitute “judgment”.

—An tAire Sláinte agus Leanaí.

SECTION 32

- 34.** In page 27, between lines 34 and 35, to insert the following subsection:

“(3) A person other than a registered retail pharmacy business who holds himself, herself or itself out as a registered retail pharmacy business shall be guilty of an offence.”.

—An tAire Sláinte agus Leanaí.

- 35.** In page 28, between lines 23 and 24, to insert the following subsection:

“(6) A person does not commit an offence under this section by using, in a public description of a registered retail pharmacy business, an expression mentioned in *subsection (5)*.”.

—An tAire Sláinte agus Leanaí.

SECTION 33

- 36.** In page 29, line 28, to delete “judgement” and substitute “judgment”.

—An tAire Sláinte agus Leanaí.

- 37.** In page 29, between lines 28 and 29, to insert the following:

“ “registered” in relation to a complaint against a pharmacist or retail pharmacy business includes a pharmacist or retail pharmacy business which was registered at the time when the circumstances constituting the grounds of the complaint occurred although not registered when the complaint is made or later.”.

—An tAire Sláinte agus Leanaí.

SECTION 34

- 38.** In page 30, subsection (8), line 6, after “committee” to insert the following:

“and a registered medical practitioner appointed under *subsection (9)*”.

—Liz McManus.

- 39.** In page 30, between lines 12 and 13, to insert the following subsection:

“(11) The registered medical practitioner has, when advising that committee, the same protections and immunities as a judge of the High Court.”.

—An tAire Sláinte agus Leanaí.

SECTION 35

- 40.** In page 30, subsection (2), lines 30 and 31, to delete “or, if not, in a form acceptable to the Council”.

[ SECTION 35 ]

—Liz McManus.

SECTION 38

41. In page 32, subsection (2)(c), line 41, to delete “specifies.” and substitute the following:

“specifies,

(d) invite the registered pharmacist or pharmacy owner to submit observations.”.

—An tAire Sláinte agus Leanaí.

42. In page 33, subsection (4), line 4, after “so” to insert the following:

“and submit observations although not invited to do so”.

—An tAire Sláinte agus Leanaí.

SECTION 43

43. In page 35, subsection (1), line 8, after “the” where it firstly occurs to insert “High”.

—Liz McManus.

SECTION 57

44. In page 40, line 1, to delete “may” and substitute “shall”.

—An tAire Sláinte agus Leanaí.

SECTION 61

45. In page 41, subsection (3), line 35, after “*section 51*” to insert “or 52”.

—An tAire Sláinte agus Leanaí.

SECTION 63

46. In page 43, between lines 10 and 11, to insert the following subsection:

“(5) The Society shall disclose any beneficial interest to the Joint Oireachtas Committee on Health and Children by 31 December in any given year.”.

—Liam Twomey.

47. In page 43, subsection (5)(a)(ii), to delete lines 29 to 31 and substitute the following:

“(II) is ascertained, directly or indirectly, by reference to the receipts or profits of a registered retail pharmacy business or a medical practice, or directly or indirectly by reference to any arrangement between the persons referred to in *subsection (2)(a)* of *section 64* providing for, acknowledging or regulating a financial benefit to any of them arising from, or facilitated by, the level of the rent or other consideration concerned, or both,”.

—Liz McManus.

[ SECTION 64 ]

SECTION 64

**48.** In page 44, subsection (1)(b), to delete lines 24 to 26 and substitute the following:

“(ii) share a common public entrance with each other,

if there is an arrangement of the kind described in *subsection (2)*.”

—An tAire Sláinte agus Leanaí.

**49.** In page 44, subsection (1)(b), to delete lines 25 and 26.

—Liz McManus.

**50.** In page 44, lines 27 to 36, to delete subsection (2) and substitute the following:

“(2) A registered pharmacist, an owner of a retail pharmacy business, a registered medical practitioner, or a medical practice shall not enter into an arrangement amongst themselves which provides for, acknowledges or regulates a financial benefit accruing to any of them arising from the prescription and dispensing of medicinal products, or arising from or facilitated by the co-location or juxtaposition described in *subsection (1)*, or both.”

—Liz McManus.

SECTION 65

**51.** In page 45, between lines 35 and 36, to insert the following:

““premises” is not restricted to land and buildings;”

—An tAire Sláinte agus Leanaí.

**52.** In page 45, between lines 35 and 36, to insert the following:

““premises” includes vehicles, craft, containers, boats, hovercraft or aircraft;”

—Liz McManus.

**53.** In page 45, paragraph (a), line 37, before “a” to insert “computer data;”

—Liz McManus.

SECTION 66

**54.** In page 48, subsection (3)(n), line 11, after “facilities” to insert the following:

“or courier facilities or other means of transportation”

—Liz McManus.

SECTION 71

**55.** In page 52, subsection (3), line 11, after “capacity” to insert the following:

“including a shadow director within the meaning of section 27 of the Companies (Amendment) Act 1990”

—Liz McManus.

SECTION 72

**56.** In page 52, before section 72, but in Part 8, to insert the following new section:

[ SECTION 72 ]

“Irish Centre for Continuing Pharmaceutical Education.

72.—(1) The Irish Centre for Continuing Pharmaceutical Education is hereby established as a statutory body.

(2) The Centre shall be an independent body and its functions include the following:

(a) the maintenance of programmes of post graduate education and training in the pharmacy sector; and

(b) the enhancement of the skills and knowledge of pharmacists.

(3) In this section, “Centre” means Irish Centre for Continuing Pharmaceutical Education.”.

—John Gormley.

57. In page 52, line 31, to delete subsection (2).

—An tAire Sláinte agus Leanaí, Liz McManus.

SECTION 73

58. In page 53, line 21, to delete “is”.

—An tAire Sláinte agus Leanaí.

SCHEDULE 1

59. In page 55, paragraph 1(2), line 7, to delete “(d), and” and substitute “and (e), and”.

—An tAire Sláinte agus Leanaí.

60. In page 55, paragraph 1(2), line 8, before “and” to insert “(as read with section 10(5))”.

—An tAire Sláinte agus Leanaí.

61. In page 55, paragraph 2, between lines 23 and 24, to insert the following:

“(2) A disqualification under *subparagraph (1)(a), (c), (d) or (e)* shall not take effect until the ordinary time for appealing against the adjudication, conviction or, as the case may be, order has expired, or if an appeal is brought, it (or any further appeal) is determined in a way which upholds the adjudication, conviction or order or is abandoned.”.

—An tAire Sláinte agus Leanaí.

62. In page 55, paragraph 2, between lines 23 and 24, to insert the following:

“(2) A disqualification pursuant to an order of a court referred to in *subparagraph (1)(a), (c), (d), (e) or (f)* shall not take effect until the ordinary time for appealing against any such order has expired, or if an appeal is lodged within that time, until any such appeal, or a further appeal therefrom is determined.”.

—Liz McManus.

63. In page 56, paragraph 4(1), line 3, after “Vice-President” to insert “who shall be registered pharmacists”.

—Liz McManus.

64. In page 59, paragraph 9, between lines 6 and 7, to insert the following:

[ SCHEDULE 1 ]

“(8) A disclosure under this paragraph or *paragraph 10* shall be recorded in a register together with particulars of any interest of members of the Authority or persons to whom *paragraph 10* applies, and the register shall be available to public inspection during office hours.”.

—Liz McManus.

65. In page 60, paragraph 11, between lines 9 and 10, to insert the following:

“(4) Reference to this paragraph is inserted in Part I of the Third Schedule to the Freedom of Information Act 1997.”.

—Liz McManus.

66. In page 60, paragraph 12(2), line 14, after “surplus” to insert the following:

“including any surplus following disposal of assets”.

—An tAire Sláinte agus Leanaí.

67. In page 60, paragraph 12(2), line 14, after “surplus” to insert the following:

“including any surplus following the disposal of its assets”.

—Liz McManus.

68. In page 62, after line 44, to insert the following:

*“Accountability to Houses of the Oireachtas*

22. When required by a committee of either or both Houses of the Oireachtas, the President of the Society shall appear before the committee to account for the general administration of the Society.”.

—Liz McManus.