



An Bille Sláinte (Forálacha Ilghnéitheacha), 2016
Health (Miscellaneous Provisions) Bill 2016

Mar a ritheadh ag Dáil Éireann

As passed by Dáil Éireann



AN BILLE SLÁINTE (FORÁLACHA ILGHNÉITHEACHA), 2016
HEALTH (MISCELLANEOUS PROVISIONS) BILL 2016

Mar a ritheadh ag Dáil Éireann
As passed by Dáil Éireann

CONTENTS

PART 1

PRELIMINARY AND GENERAL

Section

1. Short title

PART 2

AMENDMENT OF IRISH MEDICINES BOARD ACT 1995

2. Definition
3. Amendment of section 6 of Act of 1995
4. Remuneration and allowances for expenses of members of Health Products Regulatory Authority
5. Amendment of section 8 of Act of 1995

PART 3

AMENDMENT OF NURSING HOMES SUPPORT SCHEME ACT 2009

6. Definition
7. Amendment of section 36 of Act of 2009
8. Amendment of Schedule 1 to Act of 2009

PART 4

AMENDMENT OF HEALTH (PRICING AND SUPPLY OF MEDICAL GOODS) ACT 2013

9. Amendment of Schedule 3 to Health (Pricing and Supply of Medical Goods) Act 2013

PART 5

AMENDMENT OF PUBLIC HEALTH (STANDARDISED PACKAGING OF TOBACCO) ACT 2015

10. Definition
11. Amendment of section 2 of Act of 2015

12. Amendment of section 6 of Act of 2015
13. Amendment of section 7 of Act of 2015
14. Amendment of section 9 of Act of 2015
15. Amendment of section 10 of Act of 2015
16. Amendment of section 13 of Act of 2015
17. Amendment of section 14 of Act of 2015

ACTS REFERRED TO

Health (Pricing and Supply of Medical Goods) Act 2013 (No. 14)

Irish Medicines Board Act 1995 (No. 29)

Nursing Homes Support Scheme Act 2009 (No. 15)

Public Health (Standardised Packaging of Tobacco) Act 2015 (No. 4)

Redress for Women Resident in Certain Institutions Act 2015 (No. 8)



**AN BILLE SLÁINTE (FORÁLACHA ILGHNÉITHEACHA), 2016
HEALTH (MISCELLANEOUS PROVISIONS) BILL 2016**

Bill

entitled

An Act to amend the Irish Medicines Board Act 1995, the Nursing Homes Support Scheme Act 2009, the Health (Pricing and Supply of Medical Goods) Act 2013 and the Public Health (Standardised Packaging of Tobacco) Act 2015; and to provide for related matters. 5

Be it enacted by the Oireachtas as follows:

PART 1 10

PRELIMINARY AND GENERAL

Short title

1. This Act may be cited as the Health (Miscellaneous Provisions) Act 2016.

PART 2

AMENDMENT OF IRISH MEDICINES BOARD ACT 1995 15

Definition

2. In this Part, “Act of 1995” means the Irish Medicines Board Act 1995.

Amendment of section 6 of Act of 1995

3. Section 6 of the Act of 1995 is amended by the deletion of subsection (5).

Remuneration and allowances for expenses of members of Health Products Regulatory Authority 20

4. The Act of 1995 is amended by the insertion of the following section after section 7:

“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 25

Minister for Public Expenditure and Reform, may from time to time determine.”.

Amendment of section 8 of Act of 1995

5. Section 8 of the Act of 1995 is amended by the deletion of subsection (7).

PART 3

5

AMENDMENT OF NURSING HOMES SUPPORT SCHEME ACT 2009

Definition

6. In this Part, “Act of 2009” means the Nursing Homes Support Scheme Act 2009.

Amendment of section 36 of Act of 2009

7. Section 36 of the Act of 2009 is amended by the insertion of the following subsection after subsection (5): 10

“(5A) The Minister may make regulations for the purposes of paragraph (f) of the definition of ‘relevant payment’ (amended by *section 8* of the *Health (Miscellaneous Provisions) Act 2016*) in paragraph 1 of Part 3 of Schedule 1 by prescribing a class or classes of *ex-gratia* payment or payments, not coming within paragraphs (a) to (e) of that definition, if— 15

(a) the class or classes of *ex-gratia* payment or payments is, or are, payment or payments made under a scheme or schemes (howsoever described) approved by the Government, and 20

(b) the Minister is satisfied, after having regard to the nature of the payment or payments referred to in paragraphs (a) to (e) of that definition and the purposes for which such payment or payments is, or are, made, that—

(i) the nature of the class or classes of *ex-gratia* payment or payments is substantially similar to the nature of one or more of those made under those paragraphs, and 25

(ii) the purpose for which the payment or payments concerned is made is substantially similar to one or more of those purposes.”.

Amendment of Schedule 1 to Act of 2009

30

8. Part 3 of Schedule 1 to the Act of 2009 is amended, in paragraph 1, by the substitution of the following definition for the definition of “relevant payment” (inserted by section 4 of the Redress for Women Resident in Certain Institutions Act 2015):

“ ‘relevant payment’ means, in relation to a person—

- (a) a payment or payments made to the person under the Scheme, made by the Government in December 2013 and for the time being administered by the Minister for Justice and Equality, providing for the making of *ex-gratia* payments to women who were admitted to and worked in a relevant institution (within the meaning of the Redress for Women Resident in Certain Institutions Act 2015), and includes any benefit provided under that Scheme, 5
- (b) an *ex-gratia* payment or payments made to the person under the terms of the Scheme referred to as the Lourdes Hospital Redress Scheme 2007, 10
- (c) an *ex-gratia* payment or payments made to the person under the terms of the Scheme established by the Minister and referred to as the Lourdes Hospital Payment Scheme,
- (d) a payment or payments made to the person under the terms of the Surgical Symphysiotomy *ex-gratia* Scheme established by the Minister and otherwise referred to as the Symphysiotomy Payment Scheme, 15
- (e) an *ex-gratia* payment or payments made to the person by the Minister or the *Conterganstiftung für behinderte Menschen* in respect of a disability caused to that person by Thalidomide, or 20
- (f) such other *ex-gratia* payment or payments as may be prescribed under section 36(5A) (inserted by *section 7* of the *Health (Miscellaneous Provisions) Act 2016*) for the purposes of this paragraph;”. 25

PART 4

AMENDMENT OF HEALTH (PRICING AND SUPPLY OF MEDICAL GOODS) ACT 2013

Amendment of Schedule 3 to Health (Pricing and Supply of Medical Goods) Act 2013

9. Schedule 3 to the Health (Pricing and Supply of Medical Goods) Act 2013 is amended, in Part 1— 30
- (a) in paragraph 1—
 - (i) in subparagraph (d), by the insertion of “subject to paragraph 2,” before “must be”, and
 - (ii) by the substitution of the following subparagraph for subparagraph (e): 35
 - “(e) must have an authorisation referred to in paragraph (a) or (b)(i), (ii), (iii) or (iv) of the definition of ‘authorisation holder’ in section 2(1).”;

and

(b) in paragraph 2, by the insertion of “or (d)” after “paragraph 1(b)”.

PART 5

AMENDMENT OF PUBLIC HEALTH (STANDARDISED PACKAGING OF TOBACCO) ACT 2015

Definition

10. In this Part, “Act of 2015” means the Public Health (Standardised Packaging of Tobacco) Act 2015. 5

Amendment of section 2 of Act of 2015

11. Section 2(1) of the Act of 2015 is amended by the insertion of the following definitions:

“ ‘calibration mark’, in relation to the retail packaging of tobacco products, means a mark which is necessary for the automated manufacture of that packaging; 10

‘cigar band’, in relation to a cigar, means a loop made of paper or foil or other material fitted around the circumference of the cigar;

‘re-sealing tab’, in relation to a unit packet of roll-your-own tobacco or other unit packet of tobacco products (other than cigarettes), means a tab for re-sealing the packet;” 15

Amendment of section 6 of Act of 2015

12. Section 6 of the Act of 2015 is amended—

(a) in subsection (1), by the substitution of “Subject to subsection (3), this Act” for “This Act”, and 20

(b) by the insertion of the following subsections after subsection (2):

“(3) A specified provision of this Act shall not apply to the sale of tobacco products manufactured or released for circulation before the date of commencement of that provision, until the first anniversary of that date, provided that on the date of their sale those tobacco products comply with the European Union (Manufacture, Presentation and Sale of Tobacco and Related Products) Regulations 2016 (S.I. No. 271 of 2016). 25

(4) In subsection (3), “specified provision of this Act” means any of the following provisions of this Act: 30

(a) subsections (1) to (5) and (7) to (12) of section 7;

(b) section 8;

(c) subsections (1) to (5) and (7) to (12) of section 9;

(d) section 10;

(e) section 11; 35

(f) section 14.”.

Amendment of section 7 of Act of 2015

13. Section 7 of the Act of 2015 is amended—

- (a) in subsection (1)(c), by the substitution of “subsections (3) to (4B)” for “subsections (3) and (4)”, 5
 - (b) by the substitution of the following subsection for subsection (3):
 - “(3) Subject to subsections (4), (4A) and (4B), the following may be printed on a cigarette packet:
 - (a) a brand name or business name or company name;
 - (b) a variant name for the cigarettes concerned; 10
 - (c) text which states the number of cigarettes contained in the packet;
 - (d) the text ‘cigarettes’;
 - (e) text indicating the contact details of the manufacturer;
 - (f) a calibration mark.”,
 - (c) in subsection (4), by the substitution of “paragraph (a) or (b) of subsection (3)” for “subsection (3)”, 15
 - (d) by the insertion of the following subsections after subsection (4):
 - “(4A) The text referred to in paragraphs (c), (d) and (e) of subsection (3) shall be printed in accordance with regulations under subsection (10) and may be printed once on the cigarette packet. 20
 - (4B) The calibration mark referred to in paragraph (f) of subsection (3)—
 - (a) shall not be visible or, if visible, be as inconspicuous as is practicable consistent with the mark’s function in the automated manufacture of the cigarette packet, and
 - (b) shall not convey (including by any electronic means) any information to the consumer of the cigarettes contained in the packet.” 25
- and
- (e) in subsection (10), by the insertion of “or text” after “name” in both places where it occurs. 30

Amendment of section 9 of Act of 2015

14. Section 9 of the Act of 2015 is amended—

- (a) in subsection (1)—
 - (i) in paragraph (c), by the substitution of “subsections (3) to (4B)” for “subsections (3) and (4)”, and 35

- (ii) in paragraph (f), by the insertion of “subject to subsection (4C),” before “not contain”,
- (b) by the substitution of the following subsection for subsection (3):
 - “(3) Subject to subsections (4), (4A) and (4B), the following may be printed on a unit packet of roll-your-own tobacco: 5
 - (a) a brand name or business name or company name;
 - (b) a variant name for the roll-your-own tobacco concerned;
 - (c) text which states the weight of tobacco in grams contained in the packet;
 - (d) the text ‘roll-your-own tobacco’; 10
 - (e) text indicating the contact details of the manufacturer;
 - (f) a calibration mark.”,
 - (c) in subsection (4), by the substitution of “paragraph (a) or (b) of subsection (3)” for “subsection (3)”,
 - (d) by the insertion of the following subsections after subsection (4): 15
 - “(4A) The text referred to in paragraphs (c), (d) and (e) of subsection (3) shall be printed in accordance with regulations under subsection (10) and may be printed once on the packet.
 - (4B) The calibration mark referred to in paragraph (f) of subsection (3)—
 - (a) shall not be visible or, if visible, be as inconspicuous as is practicable consistent with the mark’s function in the automated manufacture of the unit packet of roll-your-own tobacco, and 20
 - (b) shall not convey (including by any electronic means) any information to the consumer of the roll-your-own tobacco contained in the packet. 25
 - (4C) Paragraph (f) of subsection (1) shall not apply to a re-sealing tab if the tab—
 - (a) is transparent,
 - (b) is not coloured or marked, and
 - (c) does not have any decorative ridges, embossing or other embellishments.”, 30

and

- (e) in subsection (10), by the insertion of “or text” after “name” in both places where it occurs.

Amendment of section 10 of Act of 2015

35

15. Section 10 of the Act of 2015 is amended—

- (a) in subsection (1)—

- (i) in paragraph (c), by the substitution of “subsections (3) to (4B)” for “subsections (3) and (4)”, and
 - (ii) in paragraph (f), by the insertion of “subject to subsection (4C),” before “not contain”,
- (b) by the substitution of the following subsection for subsection (3): 5
- “(3) Subject to subsections (4), (4A) and (4B), the following may be printed on a unit packet of tobacco products (other than cigarettes and roll-your-own tobacco) including, in the case of a cigar, the cigar band (if any):
- (a) a brand name or business name or company name; 10
 - (b) a variant name for the tobacco product concerned;
 - (c) text which states the number of, or weight in grams of, the tobacco product contained in the packet;
 - (d) the text ‘cigars’, ‘cigarillos’ or ‘pipe tobacco’, as appropriate;
 - (e) text indicating the contact details of the manufacturer; 15
 - (f) a calibration mark.”,
- (c) in subsection (4), by the substitution of “paragraph (a) or (b) of subsection (3)” for “subsection (3)”,
- (d) by the insertion of the following subsections after subsection (4):
- “(4A) The text referred to in paragraphs (c), (d) and (e) of subsection (3) shall be printed in accordance with regulations under subsection (9) and may be printed once on the packet. 20
- (4B) The calibration mark referred to in paragraph (f) of subsection (3)—
- (a) shall not be visible or, if visible, be as inconspicuous as is practicable consistent with the mark’s function in the automated manufacture of the packet, and 25
 - (b) shall not convey (including by any electronic means) any information to the consumer of the tobacco product contained in the packet.
- (4C) Paragraph (f) of subsection (1) shall not apply to a re-sealing tab if the tab— 30
- (a) is transparent,
 - (b) is not coloured or marked, and
 - (c) does not have any decorative ridges, embossing or other embellishments.”, 35
- (e) by the substitution of the following subsection for subsection (9):
- “(9) The Minister may prescribe—

(a) the manner in which a name or text under subsection (3) may be printed on a unit packet or any other form of outside packaging of tobacco products other than cigarettes and roll-your-own tobacco, including the colour, font type, font size, positioning and appearance of such a name or text, and

5

(b) without prejudice to the generality of paragraph (a) in so far as that paragraph relates to tobacco products which are cigars, prescribe the manner in which cigar bands may be placed around cigars and the information which may be contained on such cigar bands.”,

and

10

(f) by the insertion of the following subsection after subsection (10):

“(11) This section applies to the retail packaging of tobacco products (other than cigarettes and roll-your-own tobacco) that are intended for sale by retail in the State.”.

Amendment of section 13 of Act of 2015

15

16. Section 13(1) of the Act of 2015 is amended—

(a) by the insertion of “, or other text,” after “or company name”, and

(b) by the insertion of “, or calibration mark,” after “or similar identification mark”.

Amendment of section 14 of Act of 2015

17. Section 14 of the Act of 2015 is amended—

20

(a) by the substitution of “, or calibration mark or re-sealing tab, printed on or affixed to” for “printed on”, and

(b) in paragraph (b)(v), by the insertion of “subject to subsections (1)(f) and (4C) of section 9 and subsections (1)(f) and (4C) of section 10,” before “removable tabs”.

An Bille Sláinte (Forálacha Ilghnéitheacha),
2016

BILLE

(mar a ritheadh ag Dáil Éireann)

dá ngairtear

Acht do leasú an Achta um Bord Leigheasra na hÉireann, 1995, an Achta fán Scéim um Thacaíocht Tithe Banaltrais, 2009, an Achta Sláinte (Earraí Liachta a Phraghsáil agus a Sholáthar), 2013 agus an Achta Sláinte Poiblí (Pacáistiú Caighdeánaithe Tobac), 2015; agus do dhéanamh socrú i dtaobh nithe gaolmhara.

*Ritheadh ag Dáil Éireann,
6 Nollaig, 2016*

Health (Miscellaneous Provisions) Bill 2016

BILL

(as passed by Dáil Éireann)

entitled

An Act to amend the Irish Medicines Board Act 1995, the Nursing Homes Support Scheme Act 2009, the Health (Pricing and Supply of Medical Goods) Act 2013 and the Public Health (Standardised Packaging of Tobacco) Act 2015; and to provide for related matters.

*Passed by Dáil Éireann,
6th December, 2016*

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ó
FOILSEACHÁIN RIALTAIS,
52 FAICHE STIABHNA, BAILE ÁTHA CLIATH 2.
(Teil: 01 - 6476834 nó 1890 213434; Fax: 01 - 6476843)
nó trí aon díoltóir leabhar.

DUBLIN
PUBLISHED BY THE STATIONERY OFFICE
To be purchased from
GOVERNMENT PUBLICATIONS,
52 ST. STEPHEN'S GREEN, DUBLIN 2.
(Tel: 01 - 6476834 or 1890 213434; Fax: 01 - 6476843)
or through any bookseller.

€2.54

ISBN 978-1-4064-6086-5



9 781406 460865