



# **DÁIL ÉIREANN**

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## **AN BILLE SLÁINTE (EARRAÍ LIACHTA A PHRAGHSÁIL AGUS A SHOLÁTHAR), 2012 HEALTH (PRICING AND SUPPLY OF MEDICAL GOODS) BILL 2012**

### **LEASUITHE COISTE COMMITTEE AMENDMENTS**

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# DÁIL ÉIREANN

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## AN BILLE SLÁINTE (EARRAÍ LIACHTA A PHRAGHSÁIL AGUS A SHOLÁTHAR), 2012 —ROGHFHOCHOISTE

### HEALTH (PRICING AND SUPPLY OF MEDICAL GOODS) BILL 2012 —SELECT SUB-COMMITTEE

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#### *Leasuithe Amendments*

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#### SECTION 5

1. In page 14, subsection (3)(b), lines 30 and 31, to delete all words from and including “the” in line 30 down to and including “run” in line 31 and substitute the following:

“the running of the period of 180 days referred to in *subsection (2)* is, upon the giving of the notice referred to in *paragraph (a)* to the applicant, suspended”.

—An tAire Sláinte.

2. In page 15, subsection (5), between lines 8 and 9, to insert the following:

“(d) is not a medicinal product in the anti-epileptic drug class, used in the treatment of persons with epilepsy for the purpose of preventing seizures.”.

—Billy Kelleher, Caoimhghín Ó Caoláin.

3. In page 15, subsection (6), between lines 22 and 23, to insert the following:

“(d) is not a medicinal product in the anti-epileptic drug class, used in the treatment of persons with epilepsy for the purpose of preventing seizures.”.

—Billy Kelleher, Caoimhghín Ó Caoláin.

4. In page 15, subsection (7), between lines 43 and 44, to insert the following:

“(f) the medicinal product is in the anti-epileptic drug class, used in the treatment of persons with epilepsy for the purpose of preventing seizures.”.

—Billy Kelleher, Caoimhghín Ó Caoláin.

5. In page 16, subsection (8), between lines 13 and 14, to insert the following:

“(f) the medicinal product is in the anti-epileptic drug class, used in the treatment of persons with epilepsy for the purpose of preventing seizures.”.

—Billy Kelleher, Caoimhghín Ó Caoláin.

6. In page 17, between lines 4 and 5, to insert the following subsection:

[ SECTION 5 ]

“(15) (a) The Board shall not under *subsection (2)(a)* or *(4)(a)* add a medicinal product to a group of interchangeable medicinal products if the medicinal products are in the anti-epileptic drug class, used in the treatment of persons with epilepsy for the purpose of preventing seizures.

(b) The Board shall not under *subsection (2)(b)* or *(4)(b)* add a group of medicinal products to the list of interchangeable medicinal products if the group of medicinal products are in the anti-epileptic drug class, used in the treatment of persons with epilepsy for the purpose of preventing seizures.”.

—Caoimhghín Ó Caoláin.

SECTION 15

7. In page 22, to delete lines 19 and 20 and substitute the following:

“prescription ought not to be dispensed because to do so may be prejudicial to—

(a) the health of the patient for whom the prescription was written, or

(b) the health or safety of members of the public.”.

—An tAire Sláinte.

SECTION 18

8. In page 24, subsection (3)(b), lines 33 and 34, to delete all words from and including “the” in line 33 down to and including “run” in line 34 and substitute the following:

“the running of the period of 180 days referred to in *subsection (2)* is, upon the giving of the notice referred to in *paragraph (a)* to the applicant, suspended”.

—An tAire Sláinte.

SECTION 19

9. In page 25, subsection (1), line 27, after “decision” to insert “and to prescribers and pharmacists”.

—Billy Kelleher.

10. In page 25, subsection (2), line 32, after “decision” to insert “and to prescribers and pharmacists”.

—Billy Kelleher.

11. In page 25, lines 33 to 36, to delete subsection (3) and substitute the following:

“(3) The Executive may—

(a) in the case of a relevant decision which falls within *paragraph (a)* or *(e)* of the definition of “relevant decision” in *subsection (8)*, specify a date, or the occurrence of an event, from which the relevant decision shall take effect, and

[ SECTION 19 ]

- (b) in the case of a relevant decision which falls within *paragraph (d)* of that definition, specify a date, being a date after the expiration of the period of 28 days immediately following the Executive's compliance with *subsection (1)* in respect of the relevant decision, from which the relevant decision shall take effect.”.

—An tAire Sláinte.

SECTION 21

12. In page 27, subsection (2), lines 28 to 30, to delete paragraphs (d) and (e) and substitute the following:

- “(d) the potential budget impact of the item if it were to become a listed item,
- (e) the ability of suppliers of the item to meet patient demand for the item if it were to become a listed item,
- (f) the resources available to the Executive, and
- (g) the terms of any agreement in place (whether entered into before, on or after the commencement of this section) between the Executive and any representative body of the suppliers of drugs, medicines or medicinal or surgical appliances where the agreement relates, whether directly or indirectly, to the price of the item.”.

—An tAire Sláinte.

SECTION 24

13. In page 28, subsection (3), lines 39 to 41, to delete paragraphs (d) and (e) and substitute the following:

- “(d) the relevant prices of therapeutically similar listed items,
- (e) the resources available to the Executive, and
- (f) the terms of any agreement in place (whether entered into before, on or after the commencement of this section) between the Executive and any representative body of the suppliers of drugs, medicines or medical or surgical appliances where the agreement relates, whether directly or indirectly, to the price of one or more of those items.”.

—An tAire Sláinte.

SECTION 32

14. In page 34, lines 1 to 4, to delete paragraph (c) and substitute the following:

- “(c) in section 35(1) by inserting the following after paragraph (e):

“(ea) a failure to comply with *Chapter 2* or *3* of *Part 2*, or *Part 3*, of the *Health (Pricing and Supply of Medical Goods) Act 2013*,

(eb) a failure to comply with any duties referred to in section 18(1A) imposed on the pharmacist by regulations made under section 18.”,

and

[ SECTION 32 ]

(d) in section 36(1)—

(i) in paragraph (a), by deleting “and 2006, or” and substituting “and 2006,”,

(ii) in paragraph (c)(ii), by deleting “paragraph (b).” and substituting “paragraph (b),” and

(iii) by inserting the following after paragraph (c):

“or

(d) the pharmacy owner has failed to comply with any of the duties referred to in section 18(1A) imposed on the pharmacy owner by regulations made under section 18.”.”.

—An tAire Sláinte.

SCHEDULE 1

**15.** In page 36, between lines 33 and 34, to insert the following:

“5. In respect of medicines already included within a group of interchangeable medicines subject to an immaterial change, the materiality of which shall be determined by the Board, such medicines may be exempted by the Board from the notification requirements as set out at *paragraph 2.*”.

—Billy Kelleher.