An Bille Sláinte (Earraí Liachta a Phraghsáil agus a Sholáthar) (Leasú), 2018

Health (Pricing and Supply of Medical Goods) (Amendment) Bill 2018

Mar a tionscnaíodh

As initiated

[No. 33 of 2018]

AN BILLE SLÁINTE (EARRAÍ LIACHTA A PHRAGHSÁIL AGUS A SHOLÁTHAR) (LEASÚ), 2018
HEALTH (PRICING AND SUPPLY OF MEDICAL GOODS) (AMENDMENT) BILL 2018

Mar a tionscnaíodh

As initiated

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[No. 33 of 2018]

Act Referred to

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

AN BILLE SLÁINTE (EARRAÍ LIACHTA A PHRAGHSÁIL AGUS A SHOLÁTHAR) (LEASÚ), 2018
HEALTH (PRICING AND SUPPLY OF MEDICAL GOODS) (AMENDMENT) BILL 2018

Bill

entitled

An Act to amend the Health (Pricing and Supply of Medical Goods) Act 2013 to establish specific criteria applicable for orphan medicinal products for the purposes of the Health Service Executive making a relevant decision regarding adding an item to the Reimbursement List.

Be it enacted by the Oireachtas as follows:

Definitions

1. In this Act—

"Orphan Medicinal Product" means a medicinal product designated as such by the European Commission under the terms and conditions of Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products;

"Principal Act" means the Health (Pricing and Supply of Medical Goods) Act 2013.

Amendment of section 2 of Principal Act

2. Section 2 of the Principal Act is amended by the insertion of the following definition:

" 'Orphan Medicinal Product' means a medicinal product designated as such by the European Commission under the terms and conditions of Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products.".

Amendment of section 19 of Principal Act

3. Section 19 of the Principal Act is amended by the insertion of the following in subsection (5) after "the relevant decision.":

"For the avoidance of doubt, any such guidelines which include a threshold incremental cost-effective ratio or similar assessment shall not be relevant in the case of Orphan Medicinal Products.".

Amendment of Schedule 3 of Principal Act

4. Schedule 3 of the Principal Act is amended by the following part after Part 3:

"PART 4

ORPHAN MEDICINAL PRODUCTS

The Executive shall exclusively have regard to— 5

(a) the health needs of the public,

(b) the cost-effectiveness of meeting health needs by supplying the item, concerned rather than providing other health services to the same patient population,

(c) the availability and suitability of items for supply or reimbursement, or both, under section 59 of the Act of 1970, 10

(d) the proposed costs, benefits and risks of the item relative to providing other health services to the same patient population, and the level of certainty in relation to costs, benefits and risks provided through evidence or outcomes-based elements of the proposed commercial offer, 15

(e) the potential or actual budget impact of the item or listed item,

(f) the clinical need for the item or listed item,

(g) the appropriate level of clinical supervision required in relation to the item to ensure patient safety, 20

(h) the efficacy (performance in trial, insofar as can be deduced from limited data), effectiveness (performance in real situations) and added therapeutic benefit against existing standards of treatment how much better it treats a condition than existing therapies), if any, or against unmet patient needs, 25

(i) the views of any relevant patient organisation, patient advocacy group or individual patients,

(j) severity of the disease and level of unmet need,

(k) the resources available to the Executive, and

(l) the availability of the medicine in other European countries.". 30

Short title and citation

5. This Act may be cited as the Health (Pricing and Supply of Medical Goods) (Amendment) Act 2018.

An Bille Sláinte (Earraí Liachta a Phraghsáil agus a Sholáthar) (Leasú), 2018

BILLE

(mar a tionscnaíodh)

dá ngairtear

Acht do leasú an Achta Sláinte (Earraí Liachta a Phraghsáil agus a Sholáthar), 2013 chun critéir shonracha, is infheidhme maidir le táirgí íocshláinte dílleachta, a bhunú chun go dtabharfaidh Feidhmeannacht na Seirbhíse Sláinte breith iomchuí maidir le mír a chur leis an Liosta Aisíocaíochta.

An Teachta Seán Ó Breasail a thug isteach,

22 *Márta,* 2018

Health (Pricing and Supply of Medical Goods) (Amendment) Bill 2018

BILL

(as initiated)

entitled

An Act to amend the Health (Pricing and Supply of Medical Goods) Act 2013 to establish specific criteria applicable for orphan medicinal products for the purposes of the Health Service Executive making a relevant decision regarding adding an item to the Reimbursement List.

Introduced by Deputy John Brassil,

22*nd March,* 2018

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