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

Meabhrán Mínitheach
Explanatory Memorandum

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EXPLANATORY MEMORANDUM

Purpose of the Bill

This Bill has the following purposes:

- To amend the *Irish Medicines Board Act* 1995 to allow for the payment of fees to members of the Health Products Regulatory Authority (formerly the Irish Medicines Board), as such fees are payable to the members of other boards;
- To amend the *Nursing Homes Support Scheme Act 2009* in order to exclude certain ex-gratia payments which have been, or will in the future be made to individuals under specific schemes approved by Government, for the purpose of assessment of means under the *Nursing Homes Support Scheme Act 2009*;
- To amend the *Health (Pricing and Supply of Medical Goods) Act 2013* so that over-the-counter medicinal products, including emergency contraception and nicotine replacement products, can continue to be reimbursed to medical card holders after June 2016. Otherwise, medical card patients will have no way to access such products without charge (other than the prescription charge);
- To amend sections 2, 7, 9, 10, 13 and 14 of the *Public Health (Standardised Packaging of Tobacco) Act 2015* to provide by way of regulations for a number of elements relating to the appearance of tobacco packaging. The regulation of the appearance of the packaging is intended to contribute to improving public health by:
  - reducing the appeal of tobacco products to consumers;
  - increasing the effectiveness of health warnings on the retail packaging of tobacco products;
  - reducing the ability of the packaging of tobacco products to mislead consumers about the harmful effects of smoking.

The amendments to the Act of 2015 in this Bill set out further provisions in relation to retail packaging of tobacco products, some of which are of a technical and practical nature and some of which seek to provide basic information to the consumer.

Financial Implications of the Bill

There is no additional cost to the Exchequer relating to paying Board members of the Health Products Regulatory Authority, as the Authority is self-funding. The sum approved by the Department of Public Expenditure

and Reform for payment to members is €7,695 per annum. The cost to the Authority will be approximately €61,560 per annum.

It is estimated that the cost to the State of amendments to the *Nursing Homes Support Scheme Act 2009* will be minimal as the majority of individuals already have medical cards, if these had been requested, due to their medical condition. Many of the women who have undergone a symphysiotomy are elderly and it is known that some are already in nursing homes due to either old age or diminished mental capacity.

Allowing reimbursement of certain over-the-counter medicines under the GMS and community drug schemes will give rise to some additional cost from loss of prescription charges over time, but this is not expected to be significant.

There are no additional costs to the Exchequer envisaged for the proposed amendments to the *Public Health (Standardised Packaging of Tobacco) Act 2015.*

Background

PART 1 contains the short title of the Bill. No commencement date is included, which means that all sections of the Bill will be automatically commenced on enactment.

PART 2 - *Amendment of the Irish Medicines Board Act 1995*

Currently, under section 8 (7) of the *Irish Medicines Board Act 1995*, as amended only the Chairman of the Health Products Regulatory Authority (HPRA, formerly the Irish Medicines Board) is entitled to a fee. There is an onerous responsibility and significant time commitment placed on members of the Authority. The Department of Public Expenditure and Reform has advised in its Guidelines on appointments to State Boards that in general, for fees to be payable to the chairperson or members of a board, an enabling provision in the legislation governing the State body concerned is required. Such a provision typically specifies that "members may be paid such remuneration (if any) which the sponsor Minister, with the consent of the Minister for Public Expenditure and Reform, may determine". Members will be given the option to waive their fees and the One Person One Salary will apply. This Part will delete section 8 (7) of the Act. It will also introduce a new section7A giving power to the Minister, with the consent of the Minister for Public Expenditure and Reform, to pay a fee to all Board members.

PART 3 - *Amendment of the Nursing Homes Support Scheme Act 2009*

A number of groups within the State have been in receipt, or will receive, ex-gratia payments as a result of Government Decisions, which acknowledge the hardship, pain and suffering which these individuals underwent. The relevant schemes are outlined below:-

- Government approval was given in April 2007 (S180/20/10/0699A) to the establishment of a non-statutory, ex-gratia Lourdes Hospital Redress Board, based on proposals prepared by Judge Maureen Harding Clark for women who underwent clinically unnecessary hysterectomy or bilateral oophorectomy, or removal of a single functioning ovary. The work of the Redress Board concluded in January 2009, having made awards to 119 women.
- Government Decision S180/20/10/0699A of 23 July 2013 agreed the establishment of the Lourdes Hospital Payment Scheme to compensate those women who were excluded on age grounds alone from the Lourdes Hospital Redress Scheme. This group comprised

women who were over 40 at the time of the Redress Scheme and who had undergone an unnecessary bilateral oophorectomy or removal of the remaining single functioning ovary. The Payment Scheme is currently underway and 45 women have been granted awards to date, with a small number of cases to be determined.

- Government Decision S 180/20/10/1787 of 1 July 2014 agreed the establishment of the Scheme for women who underwent surgical symphysiotomy. A further Decision (of the same number of 29/10/2014) extended the ex-gratia scheme to include women who underwent pubiotomy.
- Government Decision S 18873 of 13 December 1974 agreed to pay a lump sum and monthly payments to Irish survivors of thalidomide and payments are also being made by the German Contergan Foundation to these individuals. Another Government Decision, S180/20/10/1311 of 27 April, 2010, approved further lump sum payments to 32 survivors of thalidomide, with further payment of an annual lump sum, equivalent to the German annual payment which commenced in 2009.
- The Bill will also amend section 36 of the 2009 Act, giving regulation making power to the Minister to allow for an exemption for other similar groups that may receive ex-gratia payments from being taken into consideration for support under the Nursing Homes Support Scheme (Fair Deal), provided such schemes have been approved by Government.

A person should not be disadvantaged because of acceptance of an award under these Schemes. Applications under Fair Deal are means tested and the individuals or their partners could be over the income threshold for availing of the Nursing Homes Support Scheme (NHSS) supports, because of their ex-gratia awards. The proposal will not give access to free nursing home care to the various groups, but it will merely mean that the awards/ payments they receive will be ignored for the purpose of assessment under the NHSS.

PART 4 - *Amendment of the Health (Pricing and Supply of Medical Goods) Act 2013*

The Health (Pricing and Supply of Medical Goods) Act 2013 sets out statutory procedures governing the supply, reimbursement and pricing of medicines and other items to patients under the GMS and community drugs schemes. Part 1 of Schedule 3 sets out the criteria which apply to medicinal products for the purposes of decisions on reimbursement, including that such products must be ordinarily supplied to the public only on foot of a prescription.

It is necessary to amend Part 1 of Schedule 3 to ensure that over-the-counter products, which do not require a prescription, continue to be available under the GMS and community drug schemes. The amendment proposed will allow the HSE disapply the criterion regarding prescription only medicines when considered appropriate in the interests of patient safety or public health.

Paragraph 1(e) of Part 1 of Schedule 3 of the *Health (Pricing and Supply of Medical Goods) Act 2013 s*pecifies that medicinal products must have a marketing authorisation referred to in paragraph (a) of the definition of "authorisation holder" in section 2(1) of the Act. The reference to paragraph (a) is unintentionally restrictive as it excludes products which are authorised by the European Medicines Agency and parallel - imports.

It was never the intention to exclude such products and any such inference would be contrary to free trade principles.

The requirement now is to amend the 2013 Act so that over-the-counter medicinal products, including emergency contraception and nicotine replacement products, can continue to be reimbursed after June 2016. Otherwise, medical card patients will have no way to access such products without charge (other than the prescription charge).

PART 5 - *Amendment of the Public Health (Standardised Packaging of Tobacco) Act 2015*

The *Public Health (Standardised Packaging of Tobacco) Act, 2015* was enacted on the 10th of March 2015. Section 2 of the Act sets out definitions, section 7 deals with retail packaging of cigarettes, section 9 with roll-your-own tobacco, other tobacco products including cigars are dealt with in section 10, presentation of tobacco products in section 13 and features of retail packaging in section 14.

The Act currently provides for a number of elements to be prescribed by the Minister including: the colour of the outer and inner surfaces of tobacco packaging, the form and manner of barcodes and the manner in which a name may be printed on tobacco products.

While developing regulations for tobacco packaging it has come to the Minister's attention that Ireland needs to provide for a number of other matters in regulation relating to the appearance of tobacco packaging. The other matters include text in a prescribed form to indicate the type and weight or number of tobacco products contained in the packet, the inclusion of a tab to allow consumers to reseal the pack (excluding cigarette packs) , the inclusion of a calibration mark which may be necessary for the automated production of the packaging, contact details of the manufacturer and additional information on cigar bands.

Provisions of the Bill

The Bill is 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."

PART 1 – *Preliminary and General*

Section 1 provides for the short title of the Act.

PART 2 – *Amendment of the Irish Medicines Board Act 1995*

Section 2 states that the definition of the "Act of 1995" in this Part means the *Irish Medicines Board Act 1995*.

Section 3 amends section 6 of the *Irish Medicines Board Act 1995* by the deletion of subsection (5). This provided that only the Chairperson of the Board could receive a fee for being a member of the Board.

Section 4 inserts a new section 7A after section 7 of the Act to provide that fees may be paid to Board Members of the Health Products Regulatory Authority from the Authority's resources, as may be determined by the Minister for Health with the consent of the Minister for Public Expenditure and Reform.

Section 5 amends section 8, of *the Irish Medicines Board Act 1995* by the deletion of subsection (7). This subsection had stated that only the Chairperson of the Board could be remunerated.

PART 3 – *Amendment of the Health Nursing Homes Support Scheme Act 2009*

Section 6 states that the definition of the "Act of 2009" in this part is the *Nursing Homes Support Scheme Act 2009*.

Section 7 amends section 36 of the Act of 2009 to allow the Minister to make regulations to exempt certain ex-gratia payments, under schemes which have been approved by Government, from being taken into consideration for assessment of means for the purpose of financial supports under the Act.

Section 8 amends Schedule 1 to the Act of 2009 to provide an extended definition of "relevant payment" (inserted by section 4 of the Redress for Women Resident in Certain Institutions Act 2015), to include payments to:

- women under the Lourdes Hospital Redress Scheme, which was approved by Government in 2007;
- women under the Lourdes Hospital Payment Scheme, which was approved by Government in 2013;
- women under the Symphysiotomy Payment Scheme, which was approved by Government in 2014;
- individuals in relation to disability caused by thalidomide, which are made by either the Minister for Health or by the German Contergan Foundation and which were agreed by Government in 1974 or in 2010.

PART 4 – *Amendment of Health (Pricing and Supply of Medical Goods) Act 2013*

Section 9 amends Schedule 3 to the *Health (Pricing and Supply of Medical Goods) Act 2013* to provide that the HSE may consider non-prescription medicinal products, such as emergency contraception products and nicotine replacement therapies, for reimbursement where this is considered to be in the interest of patient safety and public health. This section also clarifies that all medicinal products authorised by the European Medicines Agency, including parallel imports, are eligible for consideration for reimbursement.

PART 5 - *Amendment of Public Health (Standardised Packaging of Tobacco) Act 2015*

Section 10 sets out the definition of "Act of 2015" as meaning the *"Public Health (Standardised Packaging of Tobacco) Act 2015.*

Section 11 – (*Amendment of section 2 of the Act of 2015 – Interpretation*)

This section inserts three new definitions namely, "calibration mark", "cigar band" and "re-sealing tab".

Section 12 – (*Amendment of section 7 of the Act of 2015 – Retail Packaging of cigarettes*).

This section allows for the following elements to appear once on a cigarette pack; the word "cigarettes", the number of cigarettes in the pack, contact details of the manufacturer, the form of these elements to be prescribed in regulations. The section also allows for the inclusion of a calibration mark if it is necessary for the automated manufacture of the packaging.

Section 13 – (*Amendment of section 9 of the Act of 2015 – Retail Packaging of roll-your-own tobacco*).

This section allows for the following to appear once on a roll-your-own pack; the words "roll-your-own tobacco", the weight of the tobacco, contact details of the manufacturer, the form of these elements to be prescribed in regulations. The section allows for the inclusion of a calibration mark if it is necessary for the automated manufacture of the packaging. This section also permits the inclusion of a plain and transparent re-sealing tab in order for the consumer to re-seal the pack if necessary.

Section 14 – (*Amendment of section 10 of the Act of 2015 – Retail Packaging of other tobacco products*).

This section allows for the following elements to appear once on the packaging of other tobacco products; the words "cigars" or "cigarillos" or "pipe tobacco", the number of or weight in grams of tobacco product, contact details of the manufacturer, the form of these elements to be prescribed in regulations. The section allows for the inclusion of a calibration mark if it is necessary for the automated manufacture of the packaging and permits the inclusion of a plain and transparent re-sealing tab in order for the consumer to re-seal the pack if required. This section also provides for the prescribing of certain requirements for cigar bands i.e. the manner which they may be placed and the information to be contained on them.

Sections 15 & 16 – (*Amendment to section 13 and 14 of the Act of 2015*)

These amendments are consequential amendments arising from the preceding provisions.

Wt. —. 607. 1/16. Essentra. (56811). Gr. 30-15.