



STATUTORY INSTRUMENTS.

S.I. No. 576 of 2016.



HEALTH (REIMBURSEMENT LIST) (APPLICATION FEES)
REGULATIONS 2016

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I, SIMON HARRIS, Minister for Health, in exercise of the powers conferred on me by section 29(1)(b) of the Health (Pricing and Supply of Medical Goods) Act 2013 (No. 14 of 2013), with the consent of the Minister for Public Expenditure and Reform, hereby make the following regulations:

1. (1) These Regulations may be cited as the Health (Reimbursement List) (Application Fees) Regulations 2016.

(2) These Regulations come into operation on 1 December 2016.

2. In these Regulations—

“generic medicinal product” has the same meaning as it has in Directive 2001/83/EC;

“line extension”, in relation to a medicinal product that is a listed item, means an alteration in the presentation, physical state, volume, dosage unit, strength, manner of administration or pack size of that medicinal product;

“line extension or upgrade”, in relation to a medical device that is a listed item, means an alteration in the presentation, design, size, manner of use or materials used in the manufacture of that medical device;

“new chemical entity” means a chemical entity that has not previously been approved for inclusion on the Reimbursement List;

“parallel import licence” has the same meaning as it has in the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007);

“parallel import medicinal product” means a medicinal product that is the subject of a parallel import licence.

3. The amount specified in column (3) of the Schedule opposite a particular reference number in column (1) thereof is prescribed as the fee payable by a supplier to the Executive in respect of an application under section 18(1) of the Health (Pricing and Supply of Medical Goods) Act 2013 (No. 14 of 2013) to add an item of a type specified in column (2) of the Schedule at that reference number to the Reimbursement List.

*Notice of the making of this Statutory Instrument was published in
“Iris Oifigiúil” of 2nd December, 2016.*

SCHEDULE

Reference (1)	Type of Item (2)	Amount (3)
1	A medicinal product which is comprised of a new chemical entity	€5,000.00
2	A generic medicinal product	€500.00
3	A parallel import medicinal product	€500.00
4	A medical device	€500.00
5	A line extension of a medicinal product that is a listed item	€500.00
6	A line extension or upgrade of a medical device that is a listed item	€250.00
7	A medicinal product or medical device that has been renamed since it was added to the Reimbursement List	€100.00

The Minister for Public Expenditure and Reform consents to the making of the foregoing Regulations.



GIVEN under the Official Seal of the Minister for Public Expenditure and Reform,
30 November 2016.

PASCHAL DONOHOE,
Minister for Public Expenditure and Reform.



GIVEN under my Official Seal,
30 November 2016.

SIMON HARRIS,
Minister for Health.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation.)

These Regulations provide a statutory basis for fees charged by the HSE in respect of their reasonable administrative costs in assessing applications by manufacturers for the inclusion of their products (primarily drugs) on its Reimbursement List.

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