Number 14 *of* 2013

HEALTH (PRICING AND SUPPLY OF MEDICAL GOODS) ACT 2013

ARRANGEMENT OF SECTIONS

Acts Referred to

Dentists Act 1985	1985, No. 9
Health (Miscellaneous Provisions) Act 2001	2001, No. 14
Health Act 1970	1970, No. 1
Irish Medicines Board Act 1995	1995, No. 29
Medical Practitioners Act 2007	2007, No. 25
Nurses and Midwives Act 2011	2011, No. 41
Pharmacy Act 2007	2007, No. 20

Number 14 *of* 2013

HEALTH (PRICING AND SUPPLY OF MEDICAL GOODS) ACT 2013

AN ACT TO ESTABLISH A LIST OF GROUPS OF INTER-CHANGEABLE MEDICINAL PRODUCTS WHICH MAY BE SUBSTITUTED FOR EACH OTHER IN ORDER TO ENABLE SAVINGS TO BE MADE FOR PATIENTS OR THE HEALTH SERVICE EXECUTIVE, OR BOTH, WHERE THE LOWER PRICED MEDICINAL PRODUCTS ARE SUPPLIED, TO ESTABLISH A LIST OF DRUGS, MEDICINES AND MEDICAL AND SURGICAL APPLIANCES WHICH MAY BE SUPPLIED UNDER SECTION 59 OF THE HEALTH ACT 1970, TO ESTABLISH MECHANISMS TO SET THE PRICES OF SUCH DRUGS, MEDICINES AND MEDICAL AND SURGICAL APPLIANCES WHERE THEY ARE SO SUPPLIED, TO RENAME THE IRISH MEDICINES BOARD, TO PROVIDE FOR THE CONSEQUENTIAL AMENDMENT OF OTHER ENACTMENTS; AND FOR RELATED MATTERS.

[28*th May*, 2013]

BE IT ENACTED BY THE OIREACHTAS AS FOLLOWS:

PART 1

Preliminary and General

Short title, collective citation and commencement.

1.—(1) This Act may be cited as the Health (Pricing and Supply of Medical Goods) Act 2013.

(2) The Health Acts 1947 to 2011 and *section 30* may be cited together as the Health Acts 1947 to 2013.

(3) This Act shall come into operation on such day or days as the Minister may appoint by order or orders either generally or with reference to any particular purpose or provision, and different days may be so appointed for different purposes and different provisions.

Interpretation.

2.—(1) In this Act—

"Act of 1970" means the Health Act 1970;

"Act of 2007" means the Pharmacy Act 2007;

"authorisation holder"—

(*a*) means the holder of a marketing authorisation granted pursuant to Regulation 10(1) of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007), and

(*b*) includes the holder of—

(i) a product authorisation within the meaning of those Regulations,

(ii) a parallel import licence within the meaning of those Regulations,

(iii) an authorisation granted by the Commission of the European Community under—

(I) Council Regulation (EEC) No. 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products,[1] or

(II) Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

or

(iv) an authorisation granted by the Board under Article 126a of Directive 2001/83/EC;

"Board" means the Irish Medicines Board;

"brand name", in relation to a medicinal product, means—

(*a*) a medicinal product marketed in the State under a name (not being a common name) which identifies the medicinal product to the extent that no other medicinal product is marketed in the State under that name, or

(*b*) a medicinal product marketed in the State under a common name in conjunction with another name (which may be the name of the pharmaceutical company connected with the medicinal product) which identifies the medicinal product to the extent that no other medicinal product is marketed in the State under those names,

and references in this Act to "branded" shall be construed accordingly;

"branded product" means a branded interchangeable medicinal product named on a prescription referred to in *section 7(1)*, *8(1)*, *9(1)* or *10(1)*;

[1]OJ No. L214, 24.08.1993, p. 1
[2]OJ No. L136, 30.04.2004, p. 1

"clinical exemption", in relation to a branded interchangeable medicinal product named on a prescription, means an exemption under *section 13(1)*, in so far as that prescription is concerned, from the medicinal product being substituted by a substitute medicinal product;

"common name", in relation to a medicinal product, includes any of the following:

(*a*) the international non-proprietary name of the medicinal product;

(*b*) the scientific name of the medicinal product;

(*c*) if the medicinal product contains only one active substance, the name of the active substance;

(*d*) if the medicinal product contains 2 or more active substances, the names of each of the active substances;

"community pharmacy contractor" means a pharmacist, company or other body corporate, or partnership, who has entered into an agreement with the Executive to provide community pharmacy services to eligible persons under section 59 of the Act of 1970;

"deemed application" means an application referred to in *section 18(4)* or *(5)*;

"deemed condition" means a condition which is attached to a deemed listed item by virtue of the operation of *section 17(5)* only;

"deemed listed item" means a listed item which is on the Reimbursement List by virtue of the operation of *section 17(5)* only;

"dietary food for a special medical purpose" means a food—

(*a*) specifically processed or formulated, and intended—

(i) for the dietary management of patients, and

(ii) to be used under medicinal supervision,

or

(*b*) intended for the exclusive or partial feeding of patients—

(i) with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete—

(I) ordinary foodstuff,

(II) one or more nutrients contained in ordinary foodstuff, or

(III) metabolites,

or

(ii) with other medically determined nutrient requirements whose dietary management cannot be achieved only by—

(I) modification of the normal diet,

(II) the use of a foodstuff for a particular nutritional use, or

(III) a combination of the modification of the normal diet and the use of a foodstuff for a particular nutritional use;

"Directive 2001/83/EC" means Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use,[3] as amended by—

(*a*) Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC[4],

(*b*) Commission Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community Code relating to medicinal products for human use[5],

(*c*) Directive 2004/24/EC of the European Parliament and the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use[6],

(*d*) Directive 2004/27/EC of the European Parliament and the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use[7],

(*e*) Regulation (EC) No. 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No. 726/2004[8],

(*f*) Commission Directive 2009/120/EC of 14 September 2009 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use as regards advanced therapy medicinal products[9],

(*g*) Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use[10], and

[3]OJ No. L311, 28.11.2004, p. 67
[4]OJ No. L33, 08.02.2003, p. 30
[5]OJ No. L159, 27.06.2003, p. 46
[6]OJ No. L136, 30.04.2004, p. 85
[7]OJ No. L136, 30.04.2004, p. 34
[8]OJ No. L324, 10.12.2007, p. 121
[9]OJ No. L242, 15.09.2009, p. 3
[10]OJ No. L348, 31.12.2010, p. 74

(*h*) Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products[11];

"Drug Payment Scheme" means the scheme for the time being in force administered by the Executive for the purposes of section 59(2) of the Act of 1970;

"equivalent relevant price", in relation to an item or listed item which is marketed in another Member State, means the price, in that other Member State, of the item or listed item, as the case may be, which is, in all the circumstances of the case, the nearest equivalent to the relevant price of the item or listed item, as the case may be;

"Executive" means the Health Service Executive;

"ex-factory price", in relation to a medicinal product, means the price of the product as agreed between the Executive and the supplier of that product;

"foodstuff for a particular nutritional use" means a foodstuff—

(*a*) which, owing to its special composition or manufacturing process, is clearly distinguishable from a foodstuff for normal consumption,

(*b*) which clinical evidence shows is suitable for its claimed nutritional purpose, and

(*c*) which is marketed in such a way as to indicate its suitability for its claimed nutritional purpose;

"General Medical Services Scheme" means the scheme for the time being in force administered by the Executive for the purposes of section 58 of the Act of 1970;

"group of interchangeable medicinal products" shall be construed in accordance with *section 4(1)*;

"ingredient cost", in relation to a medicinal product, means the cost of the product arrived at by adding together—

(*a*) the ex-factory price of the product, and

(*b*) the wholesale mark-up (if any) of the product;

"interchangeable medicinal product" means a medicinal product which falls within a group of interchangeable medicinal products;

"item" means a drug, medicine or medical or surgical appliance which is not on the Reimbursement List;

[11]OJ No. L174, 1.07.2011, p. 74

"listed item" means a drug, medicine or medical or surgical appliance for the time being on the Reimbursement List;

"List of Interchangeable Medicinal Products" shall be construed in accordance with *section 4(1)*;

"Long Term Illness Scheme" means the scheme for the time being in force administered by the Executive for the purposes of section 59(3) of the Act of 1970;

"medical device" means a medical device which falls within any definition of "medical device" in—

(*a*) Article 1 of Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of Member States relating to active implantable medical devices[12], as amended by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market[13],

(*b*) Article 1 of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices[14], as amended by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market, or

(*c*) Article 1 of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices[15];

"medicinal product" has the meaning assigned to it by Directive 2001/83/EC;

"Minister" means the Minister for Health;

"patient", in relation to a prescription, means the person named on the prescription and in respect of whose treatment the prescription is issued;

"pharmacist" means a registered pharmacist within the meaning of the Act of 2007;

"pharmacy owner" has the meaning assigned to it by section 2 of the Act of 2007;

[12]OJ No. L189, 20.07.1990, p. 17
[13]OJ No. L247, 21.09.2007, p. 21
[14]OJ No. L169, 12.07.1993, p. 1
[15]OJ No. L331, 07.12.1998, p. 1

"prescriber", in relation to a prescription, means the person referred to in *paragraph (a)*, *(b)* or *(c)* of the definition of "prescription" who issued the prescription;

"prescription" means a prescription issued by—

(*a*) a registered medical practitioner within the meaning of section 2 of the Medical Practitioners Act 2007 or a registered dentist within the meaning of section 2 of the Dentists Act 1985,

(*b*) a person, in another Member State, who is, in the other Member State, of equivalent status to a registered medical practitioner or registered dentist referred to in *paragraph (a)* where—

(i) the address of that person in the other Member State, as the person issuing the prescription, is shown on the prescription,

(ii) the person is not connected with any practice of dentistry or medicine in the State, and

(iii) the prescription has not been issued with a view to enabling the supply of a medicinal product by mail order,

or

(*c*) a registered nurse within the meaning of section 2(1) of the Nurses and Midwives Act 2011;

"reference price" shall be construed in accordance with *section 24*;

"reimbursement", in relation to a listed item, means the reimbursement of all or part of the cost of the listed item, and includes any other means of offsetting such cost;

"Reimbursement List" shall be construed in accordance with *section 17(1)*;

"reimbursement price" has the meaning assigned to it by regulation 2 of the Health Professionals (Reduction of Payments to Community Pharmacy Contractors) Regulations 2011 (S.I. No. 300 of 2011);

"relevant group of interchangeable medicinal products" means a group of interchangeable medicinal products which consists of, or includes, 2 or more interchangeable medicinal products which are listed items;

"relevant listed items" means all the listed items which fall within a relevant group of interchangeable medicinal products;

"relevant price"—

(*a*) in relation to an item or a listed item which is a medicinal product, means the ingredient cost of the item, and

(*b*) in relation to a listed item which is—

(i) a medical device,

(ii) a foodstuff for a particular nutritional use, or

(iii) a dietary food for a special medical purpose,

means the reimbursement price of the listed item;

"relevant scheme" means—

(*a*) the General Medical Services Scheme,

(*b*) the Drug Payment Scheme,

(*c*) the Long Term Illness Scheme, or

(*d*) any other scheme for the time being in force administered by the Executive for the purposes of section 59 of the Act of 1970;

"retail pharmacy business" means a retail pharmacy business, within the meaning of section 2 of the Act of 2007, which is registered under that Act;

"set", in relation to a reference price for a group of interchangeable medicinal products, means set under *section 24(1)* or *(2)*;

"specified", in relation to a form, means specified under *section 28*;

"substitute medicinal product", in relation to a branded interchangeable medicinal product prescribed for a person, means another interchangeable medicinal product which falls within the same group of interchangeable medicinal products as the branded interchangeable medicinal product.

(2) Any reference in a provision of this Act to an authorisation holder of a medicinal product includes a person nominated in writing by the authorisation holder to act on behalf of the authorisation holder in respect of that provision in so far as it relates to that medicinal product.

(3) For the purposes of this Act, an active substance in a medicinal product may be the same as another active substance in another medicinal product notwithstanding that the 2 medicinal products contain different salts, esters, ethers, isomers or mixtures of isomers, or the 2 medicinal products contain different complexes or derivatives of the active substance concerned, provided that the 2 active substances do not significantly differ in relation to safety or efficacy in respect of human use.

Laying of regulations.

3.—Every regulation made under this Act shall be laid before each House of the Oireachtas as soon as is practicable after it is made and, if a resolution annulling the regulation is passed by either such House within the next 21 days on which that House has sat after the regulation is laid before it, the regulation shall be annulled accordingly, but without prejudice to the validity of anything previously done thereunder.

PART 2

INTERCHANGEABLE MEDICINAL PRODUCTS

CHAPTER 1

Establishment and maintenance of List of Interchangeable Medicinal Products

Establishment, etc. of List of Interchangeable Medicinal Products.

4.—(1) The Board shall, as soon as is practicable after the commencement of this section, establish and publish on its Internet website, and maintain, a list (in this Act referred to as the "List of Interchangeable Medicinal Products"), in such form as it thinks fit, of groups of medicinal products in respect of which it is satisfied, in accordance with *section 5*, as respects each such group, that all the medicinal products which fall within the group (in this Act referred to as a "group of interchangeable medicinal products") are, for prescription purposes, interchangeable with each other.

(2) The Board shall arrange for that part of its Internet website which contains the List of Interchangeable Medicinal Products to ordinarily be accessible by members of the public.

(3) In any legal proceedings, a certificate signed by the Chief Executive of the Board, or an employee of the Board authorised by the Chief Executive to give a certificate under this subsection, stating that a medicinal product specified in the certificate—

(*a*) falls within a group of interchangeable medicinal products specified in the certificate,

(*b*) does not fall within a group of interchangeable medicinal products specified in the certificate,

(*c*) fell, at a specified date or during a specified period, within a group of interchangeable medicinal products specified in the certificate,

(*d*) did not fall, at a specified date or during a specified period, within a group of interchangeable medicinal products specified in the certificate, or

(*e*) has never fallen within any group of interchangeable medicinal products,

shall, without proof of the signature of the person purporting to sign the certificate or that the person was the Chief Executive of the Board, or an employee of the Board so authorised, as the case may be, be evidence, unless the contrary is proved, of the matters stated in the certificate.

Maintenance of List of Interchangeable Medicinal Products.

5.—(1) The authorisation holder of a medicinal product (or, where *subsection (14)* applies, a person permitted under that subsection to do so) may make an application in the specified form, accompanied by the fee (if any) prescribed in regulations made under *section 29* in respect of this section, to the Board requesting the Board—

(*a*) to add the medicinal product the subject of the application to the group of interchangeable medicinal products specified in the application, or

(*b*) to add the group of medicinal products (which must include the first-mentioned medicinal product) the subject of the application to the List of Interchangeable Medicinal Products.

(2) Subject to this section and *section 6*, where the Board receives an application under *subsection (1)*, it shall, before the expiration of a period of 180 days from the day on which it received the application or such longer period as may be required by the operation of *subsection (3)*, determine the application by—

(*a*) if *paragraph (a)* of *subsection (1)* is applicable—

(i) adding the relevant medicinal product the subject of the application to the group of interchangeable medicinal products specified in the application, or

(ii) refusing to add the medicinal product the subject of the application to the group of interchangeable medicinal products specified in the application,

(*b*) if *paragraph (b)* of *subsection (1)* is applicable—

(i) adding the group of medicinal products the subject of the application to the List of Interchangeable Medicinal Products, or

(ii) refusing to add the group of medicinal products the subject of the application to the List of Interchangeable Medicinal Products.

(3) Where the Board receives an application under *subsection (1)* but is unable to determine the application under *subsection (2)* because it requires additional information from the applicant—

(*a*) the Board shall give notice in writing to the applicant specifying the additional information that it requires from the applicant in order to determine the application, and

(*b*) 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 in the case of that application unless and until the applicant gives the Board the additional information that the Board requires to determine the application.

(4) Subject to this section and *section 6*, the Board may, of its own initiative or at the request of the Minister or the Executive—

(*a*) add a medicinal product to a group of interchangeable medicinal products, or

(*b*) add a group of medicinal products to the List of Interchangeable Medicinal Products.

(5) The Board shall not under *subsection (2)(a)* or *(4)(a)* add a medicinal product to a group of interchangeable medicinal products unless the Board is satisfied that the medicinal product—

(*a*) has the same qualitative and quantitative composition in each of its active substances as each of the active substances of the interchangeable medicinal products which currently fall within the group of interchangeable medicinal products,

(*b*) is in the same pharmaceutical form as, or in a pharmaceutical form that is appropriate for substitution for, each of the interchangeable medicinal products which currently fall within the group of interchangeable medicinal products, and

(*c*) has the same route of administration as each of the interchangeable medicinal products which currently fall within the group of interchangeable medicinal products.

(6) The Board shall not under *subsection (2)(b)* or *(4)(b)* add a group of medicinal products to the List of Interchangeable Medicinal Products unless the Board is satisfied that each medicinal product which falls within the group—

(*a*) has the same qualitative and quantitative composition in each of its active substances as each of the active substances of the other medicinal products which fall within the group,

(*b*) is in the same pharmaceutical form as, or in a pharmaceutical form that is appropriate for substitution for, each of the other medicinal products which fall within the group, and

(*c*) has the same route of administration as each of the other medicinal products which fall within the group.

(7) The Board shall not under *subsection (2)(a)* or *(4)(a)* add a medicinal product to a group of interchangeable medicinal products if the Board is satisfied that—

(*a*) there is a difference in bioavailability between the medicinal product and the interchangeable medicinal products which currently fall within the group of interchangeable medicinal products which may lead to a clinically significant difference in efficacy between them,

(*b*) the medicinal product contains more than 2 active substances,

(*c*) the device (if any) for the administration of the medicinal product has significantly different instructions for use than the devices (if any) for the administration of the interchangeable medicinal products which currently fall within the group of interchangeable medicinal products,

(*d*) the medicinal product is a biological rather than a chemical entity, or

(*e*) the medicinal product cannot be safely substituted for each of the interchangeable medicinal products which currently fall within the group of interchangeable medicinal products.

(8) 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 Board is satisfied that—

(*a*) there is a difference in bioavailability between any of the medicinal products which may lead to a clinically significant difference in efficacy between them,

(*b*) any of the medicinal products contains more than 2 active substances,

(*c*) the device (if any) for the administration of any one or more of the medicinal products has significantly different instructions for use than one or more of the other such devices,

(*d*) any of the medicinal products is a biological rather than a chemical entity, or

(*e*) any of the medicinal products cannot be safely substituted for any one or more of the other medicinal products.

(9) Subject to *section 6*, the Board shall remove from a group of interchangeable medicinal products an interchangeable medicinal product which it is satisfied—

(*a*) has ceased to fall within the definition of "medicinal product" in *section 2(1)*, or

(*b*) has permanently ceased to be marketed in the State.

(10) Subject to *section 6*, where the Board is satisfied that an interchangeable medicinal product has temporarily ceased to be marketed in the State, it may, after having regard to how long it is expected that the cesser will last and the degree of disruption that the cesser causes or may cause patients who have been using the medicinal product, remove the medicinal product from the group of interchangeable medicinal products concerned.

(11) The Board shall remove a group of interchangeable medicinal products from the List of Interchangeable Medicinal Products if, for whatever reason, only one interchangeable medicinal product falls within the group.

(12) Subject to *section 6*, where the Board is satisfied that, if an interchangeable medicinal product were not currently an interchangeable medicinal product, it would not, under *subsection (2)* or *(4)*, cause the medicinal product to become an interchangeable medicinal product, it shall remove the medicinal product from the group of interchangeable medicinal products concerned.

(13) Subject to *section 6*, where the Board is satisfied that, if a group of interchangeable medicinal products were not currently a group of interchangeable medicinal products, it would not, under *subsection (2)* or *(4)*, cause the interchangeable medicinal products which fall within the group to become a group of interchangeable medicinal products, it shall remove the group of interchangeable medicinal products from the List of Interchangeable Medicinal Products.

(14) Where a person proposes to make an application to the Board to be granted an authorisation in respect of a medicinal product such that, if the authorisation were granted, the person would be the authorisation holder (within the meaning of this Act) of the medicinal product, the Board may also permit the person to, at the same time, make an application to it under *subsection (1)* in respect of the medicinal product as if the person were already such authorisation holder, so that the Board, if it does grant such authorisation to the person, may also, at the same time, determine the application under *subsection (1)* in respect of that medicinal product.

Action to be taken by Board where it makes decision under *section 5*.

6.—(1) The Board shall, as soon as is practicable after making a relevant decision (but, in any case, not later than 14 days after making the relevant decision), give notice in writing of the relevant decision, together with its reasons for the relevant decision, to—

(*a*) in the case of a relevant decision which falls within *paragraph (a)* of the definition of "relevant decision" in *subsection (6)*, the authorisation holder of the medicinal product added or to be added to the group of interchangeable medicinal products concerned and the authorisation holders of the interchangeable medicinal products which currently fall within that group of interchangeable medicinal products,

(*b*) in the case of a relevant decision which falls within *paragraph (b)* of the definition of "relevant decision" in *subsection (6)*, the authorisation holder of the medicinal product that the Board has refused to add to the group of interchangeable medicinal products concerned,

(*c*) in the case of a relevant decision which falls within *paragraph (c)* of the definition of "relevant decision" in *subsection (6)*, the authorisation holders of the medicinal products which fall within the group of medicinal products concerned,

(*d*) in the case of a relevant decision which falls within *paragraph (d)* of the definition of "relevant decision" in *subsection (6)*, the authorisation holder of a medicinal product who made the application concerned under *section 5(1)*,

(*e*) in the case of a relevant decision which falls within *paragraph (e)* of the definition of "relevant decision" in *subsection (6)*, the authorisation holder of the medicinal product added or to be added to the group of interchangeable medicinal products concerned and the authorisation holders of the interchangeable medicinal products which currently fall within that group of interchangeable medicinal products,

(*f*) in the case of a relevant decision which falls within *paragraph (f)* of the definition of "relevant decision" in *subsection (6)*, the authorisation holders of the medicinal products which fall within the group of medicinal products added or to be added to the List of Interchangeable Medicinal Products,

(*g*) in the case of a relevant decision which falls within *paragraph (g)* of the definition of "relevant decision" in *subsection (6)*, the authorisation holder of the medicinal product removed or to be removed from the group of interchangeable medicinal products concerned, and

(*h*) in the case of a relevant decision which falls within *paragraph (h)* of the definition of "relevant decision" in *subsection (6)*, the authorisation holders of the interchangeable medicinal products which fall within the group of interchangeable medicinal products removed or to be removed from the List of Interchangeable Medicinal Products.

(2) The Board may, in a relevant decision which falls within *paragraph (a), (c), (e), (f), (g)* or *(h)* of the definition of "relevant decision" in *subsection (6)*, specify a date, or the occurrence of an event, from which the relevant decision shall take effect.

(3) *Part 1* of *Schedule 1* shall have effect where the Board proposes to make a relevant decision.

(4) The Board shall, for information purposes only, give the Executive a copy of each notice it gives under *subsection (1)*.

(5) Where a relevant decision which falls within *paragraph (g)* or *(h)* of the definition of "relevant decision" in *subsection (6)* is to take effect, the Board shall, as soon as is practicable, cause notice of the relevant decision to be published in such manner as it thinks appropriate to bring the relevant decision to the attention of prescribers and pharmacists, in particular as regards the date, or the occurrence of the event, from which the relevant decision shall take effect.

(6) In this section and *Part 1* of *Schedule 1* "relevant decision" means a decision of the Board—

(*a*) under *section 5(2)(a)(i)* to add the medicinal product referred to in that section to the group of interchangeable medicinal products referred to in that section,

(*b*) under *section 5(2)(a)(ii)* to refuse to add the medicinal product referred to in that section to the group of interchangeable medicinal products referred to in that section,

(*c*) under *section 5(2)(b)(i)* to add the group of medicinal products referred to in that section to the List of Interchangeable Medicinal Products,

(*d*) under *section 5(2)(b)(ii)* to refuse to add the group of medicinal products referred to in that section to the List of Interchangeable Medicinal Products,

(*e*) under *section 5(4)(a)* to add a medicinal product to a group of interchangeable medicinal products,

(*f*) under *section 5(4)(b)* to add a group of medicinal products to the List of Interchangeable Medicinal Products,

(*g*) under *section 5(9), (10)* or *(12)* to remove an interchangeable medicinal product from a group of interchangeable medicinal products, or

(*h*) under *section 5(13)* to remove a group of interchangeable medicinal products from the List of Interchangeable Medicinal Products.

Chapter 2

Duties of pharmacists in relation to prescriptions for interchangeable medicinal products under branded name

Scenario 1 — retail pharmacy business has in stock branded product named on prescription and one substitute medicinal product of lower cost.

7.—(1) *Subsection (2)* shall apply where a pharmacist who is working in a retail pharmacy business is presented with a prescription, by the patient for whom the prescription was issued or a person acting on behalf of the patient, for a branded interchangeable medicinal product which is not the subject of a clinical exemption and, at the time the prescription is presented, the retail pharmacy business has in stock the branded product and only one substitute medicinal product which is of lower cost to the Executive (as specified in the Reimbursement List) or the patient, as the case may be, than the branded product.

(2) The pharmacist shall offer the patient, or the person acting on behalf of the patient, as the case may be, the opportunity to agree to the pharmacist substituting the branded product with the substitute medicinal product.

(3) Where the patient, or the person acting on behalf of the patient, to whom an offer referred to in *subsection (2)* is made by a pharmacist agrees to the substitution the subject of the offer, the pharmacist shall effect the substitution.

Scenario 2 — retail pharmacy business has in stock branded product named on prescription and 2 or more substitute medicinal products of lower cost.

8.—(1) *Subsection (2)* shall apply where a pharmacist who is working in a retail pharmacy business is presented with a prescription, by the patient for whom the prescription was issued or a person acting on behalf of the patient, for a branded interchangeable medicinal product which is not the subject of a clinical exemption and, at the time the prescription is presented, the retail pharmacy business has in stock the branded product and 2 or more substitute medicinal products each of which is of lower cost to the Executive (as specified in the Reimbursement List) or the patient, as the case may be, than the branded product.

(2) The pharmacist shall offer the patient, or the person acting on behalf of the patient, as the case may be, the opportunity to agree to the pharmacist substituting the branded product with one of the substitute medicinal products chosen by the patient, or the person acting on behalf of the patient, as the case may be, with the pharmacist offering that opportunity, unless the patient, or the person acting on behalf of the patient, declines any substitution, by starting with the substitute medicinal product which is of the lowest cost to the Executive (as specified in the Reimbursement List) or the patient, as the case may be, and, if substitution is not agreed at that stage, proceeding to the substitute medicinal product which is of the next lowest cost to the Executive (as specified in the Reimbursement List) or the patient, as the case may be, and so on until substitution has been agreed or each of those substitute medicinal products has been made the subject of that opportunity without substitution being agreed, whichever first occurs.

(3) Where the patient, or the person acting on behalf of the patient, to whom an offer referred to in *subsection (2)* is made by a

pharmacist agrees to the substitution the subject of the offer, the pharmacist shall effect the substitution.

Scenario 3 — retail pharmacy business does not have in stock branded product named on prescription but does have in stock one substitute medicinal product of equal or lower cost.

9.—(1) *Subsection (2)* shall apply where a pharmacist who is working in a retail pharmacy business is presented with a prescription, by the patient for whom the prescription was issued or a person acting on behalf of the patient, for a branded interchangeable medicinal product which is not the subject of a clinical exemption and, at the time the prescription is presented, the retail pharmacy business does not currently have in stock the branded product but does have in stock only one substitute medicinal product which the pharmacist reasonably believes is of equal or lower cost to the Executive (as specified in the Reimbursement List) or the patient, as the case may be, than the branded product.

(2) The pharmacist shall offer the patient, or the person acting on behalf of the patient, as the case may be, the opportunity to agree to the pharmacist substituting the branded product with the substitute medicinal product after the pharmacist has informed the patient, or the person acting on behalf of the patient, as the case may be, that the retail pharmacy business does not presently have in stock the branded product.

(3) Where the patient, or the person acting on behalf of the patient, to whom an offer referred to in *subsection (2)* is made by a pharmacist agrees to the substitution the subject of the offer, the pharmacist shall effect the substitution.

Scenario 4 — retail pharmacy business does not have in stock branded product named on prescription but does have in stock 2 or more substitute medicinal products of equal or lower cost.

10.—(1) *Subsection (2)* shall apply where a pharmacist who is working in a retail pharmacy business is presented with a prescription, by the patient for whom the prescription was issued or a person acting on behalf of the patient, for a branded interchangeable medicinal product which is not the subject of a clinical exemption and, at the time the prescription is presented, the retail pharmacy business does not currently have in stock the branded product but does have in stock 2 or more substitute medicinal products each of which the pharmacist reasonably believes is of equal or lower cost to the Executive (as specified in the Reimbursement List) or the patient, as the case may be, than the branded product.

(2) The pharmacist shall offer the patient, or the person acting on behalf of the patient, as the case may be, the opportunity to agree to the pharmacist substituting the branded product with one of the substitute medicinal products chosen by the patient, or the person acting on behalf of the patient, as the case may be—

(*a*) after the pharmacist has informed the patient, or the person acting on behalf of the patient, as the case may be, that the retail pharmacy business does not currently have in stock the branded product, and

(*b*) with the pharmacist offering that opportunity, unless the patient, or the person acting on behalf of the patient, declines any substitution, by starting with the substitute medicinal product which is of the lowest cost to the Executive (as specified in the Reimbursement List) or the patient, as the case may be, and, if substitution is not agreed at that stage, proceeding to the substitute medicinal product which is of the next lowest cost to the Executive (as specified in the Reimbursement List) or the

patient, as the case may be, and so on until substitution has been agreed or each of those substitute medicinal products has been made the subject of that opportunity without substitution being agreed, whichever first occurs.

(3) Where the patient, or the person acting on behalf of the patient, to whom an offer referred to in *subsection (2)* is made by a pharmacist agrees to the substitution the subject of the offer, the pharmacist shall effect the substitution.

Chapter 3

Duties of pharmacists in relation to prescriptions for interchangeable medicinal products under common name

Action to be taken by pharmacist when presented with prescription for interchangeable medicinal product under common name.

11.—Where a pharmacist who is working in a retail pharmacy business is presented with a prescription, by the patient for whom the prescription was issued or a person acting on behalf of the patient, for an interchangeable medicinal product under a common name, the pharmacist shall, for the purpose of that prescription, dispense from amongst the interchangeable medicinal products which fall within the group of interchangeable medicinal products concerned and which the retail pharmacy business has in stock at the time the prescription is so presented, that medicinal product which is of the lowest cost to the Executive (as specified in the Reimbursement List) or the patient, as the case may be.

Chapter 4

Miscellaneous

No liability of pharmacist, etc., for substitution.

12.—Where a pharmacist working in a retail pharmacy business is presented with a prescription for a branded interchangeable medicinal product and substitutes, in accordance with *Chapter 2*, a substitute medicinal product for the branded interchangeable medicinal product, no action or other proceeding lies or shall be instituted against the pharmacist or the prescriber, or any other person who is responsible for the acts or omissions of the pharmacist or prescriber, as the case may be, on the ground of the substitution.

Clinical exemptions to substitution.

13.—(1) When a branded interchangeable medicinal product is prescribed for a patient and the prescriber is satisfied that the medicinal product should, for clinical reasons, be exempted from substitution in accordance with *Chapter 2*, the prescriber shall write, legibly and by hand, "do not substitute" on the prescription beside the name of the medicinal product.

(2) The Minister may make regulations to require prescribers, or a class of prescribers, who issue prescriptions for patients to whom a relevant scheme applies, to state (whether on the prescription concerned or otherwise, as specified in the regulations), whenever such a prescriber prescribes a branded interchangeable medicinal product for such a patient and then makes the medicinal product subject to a clinical exemption, his or her clinical reasons for the clinical exemption.

(3) A prescriber to whom regulations made under *subsection (2)* apply shall comply with the regulations.

(4) Where a prescriber participates in a relevant scheme in his or her capacity as a prescriber, it shall, by virtue of this subsection, be deemed a condition ("relevant condition") of that scheme that a prescriber to whom regulations made under *subsection (2)* apply shall comply with the regulations and, in any case where the prescriber does not so comply, the provisions of the scheme relating to a failure to comply with a condition of the scheme shall likewise apply to the failure to comply with the relevant condition.

Community pharmacy contractors who participate in relevant schemes.

14.—Where a community pharmacy contractor participates in any relevant scheme in his or her capacity as a community pharmacy contractor and has employees who are pharmacists, it shall, by virtue of this section, be deemed a condition ("relevant condition") of that scheme that the community pharmacy contractor shall supervise the compliance, of those employees, with the provisions of this Part applicable to pharmacists and, in any case where the community pharmacy contractor does not so supervise such compliance, the provisions of the scheme relating to failure to comply with a condition of the scheme shall likewise apply to the failure to comply with the relevant condition.

Pharmacist's discretion not to dispense is preserved.

15.—Nothing in this Part shall be construed to affect a pharmacist's discretion, when presented with a prescription, to not dispense, whether temporarily or permanently, a medicinal product in accordance with the prescription (including any substitute medicinal product) if, in his or her professional opinion as a pharmacist, the 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.

PART 3

Dispensing of Medicinal Products under Common Name where they are not Interchangeable Medicinal Products

Dispensing of medicinal products under common name where they are not interchangeable medicinal products.

16.—(1) Subject to *subsection (2)*, where a pharmacist who is working in a retail pharmacy business is presented with a prescription, by the patient for whom the prescription was issued or a person acting on behalf of the patient, for a medicinal product (not being an interchangeable medicinal product) under a common name, the pharmacist shall, for the purpose of that prescription, dispense from amongst the medicinal products which meet the requirements of that prescription and which the retail pharmacy business has in stock at the time the prescription is presented, that medicinal product which is of the lowest cost to the Executive (as specified in the Reimbursement List) or the patient, as the case may be.

(2) Where *subsection (1)* applies to a prescription but the patient for whom the prescription was issued or a person acting on behalf of the patient requests the pharmacist to dispense, from amongst the medicinal products which meet the requirements of the prescription and which the retail pharmacy business has in stock at the time the prescription is presented, a medicinal product other than the medicinal product which the pharmacist would, under *subsection (1)* and

but for this subsection, be required to dispense, the pharmacist shall dispense the medicinal product the subject of the request.

(3) *Sections 14* and *15* shall, with all necessary modifications, apply to this section as they apply to *Part 2*.

(4) *Section 26* shall, with all necessary modifications, apply to this section as it applies to *Chapter 2* of *Part 2*.

PART 4

Items that may be Supplied to Patients under section 59 of Act of 1970

Chapter 1

Establishment and maintenance of Reimbursement List

Establishment, etc. of Reimbursement List.

17.—(1) Subject to *subsection (5)*, the Executive shall, on and from the commencement of this section, establish and publish on its Internet website, and maintain in accordance with *sections 18* and *21*, a list (in this Act referred to as the "Reimbursement List"), in such form, subject to *subsection (2)*, as it thinks fit, of drugs, medicines and medical and surgical appliances for the purposes of section 59 of the Act of 1970.

(2) The Reimbursement List shall specify—

(*a*) the ingredient cost of each listed item which is a medicinal product,

(*b*) the reimbursement price of each listed item which is a medical device, a foodstuff for a particular nutritional use or a dietary food for a special medical purpose, and

(*c*) if 2 or more listed items fall within the same group of interchangeable medicinal products for which a reference price has been set, the reference price.

(3) The Executive shall arrange for that part of its Internet website which contains the Reimbursement List to ordinarily be accessible by members of the public.

(4) In any legal proceedings, a certificate signed by the chief executive officer of the Executive, or an employee of the Executive authorised by the chief executive officer to give a certificate under this subsection, stating that a drug, medicine or medical or surgical appliance specified in the certificate—

(*a*) is a listed item,

(*b*) is not a listed item,

(*c*) was, at a specified date or during a specified period, a listed item,

(*d*) was not, at a specified date or during a specified period, a listed item, or

(*e*) has never been a listed item,

shall, without proof of the signature of the person purporting to sign the certificate or that the person was the chief executive officer of the Executive, or an employee of the Executive so authorised, as the case may be, be evidence, unless the contrary is proved, of the matters stated in the certificate.

(5) A drug, medicine or medical or surgical appliance that was, immediately before the commencement of this section, listed on any list of drugs, medicines or medical or surgical appliances maintained by the Executive for the purposes of section 59 of the Act of 1970 shall, on that commencement, be deemed to be listed on the Reimbursement List, and any conditions to which the drug, medicine or medical or surgical appliance concerned was, immediately before that commencement, subject, shall also be deemed to be attached to the listing on the Reimbursement List of that drug, medicine or medical or surgical appliance, as the case may be.

Maintenance of Reimbursement List.

18.—(1) The supplier of an item may make an application in the specified form, accompanied by the fee (if any) prescribed in regulations made under *section 29* in respect of this section, to the Executive requesting the Executive to add the item to the Reimbursement List.

(2) Subject to this section and *section 19*, where the Executive receives an application under *subsection (1)*, it shall, before the expiration of a period of 180 days from the day on which it received the application or such longer period as may be required by the operation of *subsection (3)*, determine the application, after consulting such experts (if any) as it thinks fit, by—

(*a*) subject to *section 21(2)*, adding the item the subject of the application to the Reimbursement List at a price (being the ingredient cost, reimbursement price or the reference price, as the case requires) agreed with the applicant, subject to any conditions attached to such listing in accordance with *section 20*, or

(*b*) refusing to add the item the subject of the application to the Reimbursement List.

(3) Where the Executive receives an application under *subsection (1)* but is unable to determine the application under *subsection (2)* because it requires additional information from the applicant—

(*a*) the Executive shall give notice in writing to the applicant specifying the additional information that it requires from the applicant in order to so determine the application, and

(*b*) 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 in the case of that application unless and until the applicant gives the Executive the additional information that the Executive requires to so determine the application.

(4) The Executive shall, not later than the 3rd anniversary of the date of commencement of *section 17* (or such longer period expiring on or before the 5th anniversary of that commencement as the Minister permits upon the request of the Executive), treat each deemed listed item (including its relevant price and any deemed condition

attached to its listing) as if it were not on the Reimbursement List but were the subject of an application under *subsection (1)*, and *subsections (2)* and *(3)* set out in *Schedule 2* shall, for the purposes of this subsection, be deemed to be substituted for *subsections (2)* and *(3)* of this section.

(5) The Executive may at any time treat a listed item (including a listed item which was once a deemed listed item) as if it were not on the Reimbursement List but were the subject of an application under *subsection (1)* and, in any such case, *subsections (2)* and *(3)* set out in *Schedule 2* shall, for the purposes of this subsection, be deemed to be substituted for *subsections (2)* and *(3)* of this section.

(6) Subject to *section 19*, the Executive shall remove a listed item from the Reimbursement List which it is satisfied has permanently ceased to be marketed in the State.

(7) Subject to *section 19*, where the Executive is satisfied that a listed item has temporarily ceased to be marketed in the State, it may, after having regard to how long it is expected that the cesser will last and the degree of disruption that the cesser causes or may cause patients who have been using the listed item, remove the listed item from the Reimbursement List.

(8) Subject to *section 19*, where the Executive is satisfied that a listed item is marketed in the State in insufficient quantity to meet the demand in the State for the listed item, it may remove the listed item from the Reimbursement List.

(9) The supplier of an item who has made an application under *subsection (1)* in respect of the item may, by notice in writing given to the Executive at any time before the determination under *subsection (2)* of the application, withdraw the application without prejudice to his or her right to make, at a later date, another such application in respect of that item.

(10) The supplier of an item which has been removed from the Reimbursement List may make, at a later date, another application under *subsection (1)* in respect of that item.

Action to be taken by Executive where it makes decision under *section 18*.

19.—(1) The Executive shall, as soon as is practicable after making a relevant decision (but, in any case, not later than 14 days after making the relevant decision), give notice in writing of the relevant decision, together with its reasons for the relevant decision, to the supplier of the item or listed item the subject of the relevant decision.

(2) Where the Executive has made a relevant decision based on any expert opinions or recommendations, it shall attach copies of all such opinions and recommendations to the notice concerned under *subsection (1)* to be given to the supplier of the item or listed item the subject of the relevant decision.

(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

(*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.

(4) The Executive shall not make a relevant decision except in accordance with the criteria specified in *Schedule 3* that apply to the item or listed item the subject of the relevant decision.

(5) The Executive shall, in making a relevant decision, have regard to any Health Technology Assessment guidelines published by the Health Information and Quality Authority that appear to the Executive to be relevant to the relevant decision.

(6) Where the Executive determines a deemed application under *section 18(2)*—

(*a*) the deemed listed item the subject of the deemed application shall cease to be a deemed listed item, and

(*b*) a deemed condition attached to the listing of the deemed listed item shall cease to be a deemed condition,

immediately upon the supplier of the item being given notice under *subsection (1)* of the relevant decision concerned or, if *subsection (3)* applies in the case of that relevant decision, immediately upon the relevant decision taking effect.

(7) *Part 2* of *Schedule 1* shall have effect where the Executive proposes to make a relevant decision.

(8) In this section and *Part 2* of *Schedule 1* "relevant decision" means a decision of the Executive—

(*a*) under *section 18(2)(a)* to add an item to the Reimbursement List, whether or not subject to conditions,

(*b*) under *section 18(2)(a)*, as read with *section 18(4)* or *(5)*, to retain a listed item on the Reimbursement List, whether or not subject to conditions,

(*c*) under *section 18(2)(b)* to refuse to add an item to the Reimbursement List,

(*d*) under *section 18(2)(b)*, as read with *section 18(4)* or *(5)*, to remove a listed item from the Reimbursement List, or

(*e*) under *section 18(6)*, *(7)* or *(8)* to remove a listed item from the Reimbursement List.

Chapter 2

Executive may attach conditions to supply of listed items

Conditional supply of listed items.

20.—(1) The Executive may attach conditions to the supply or reimbursement, under section 59 of the Act of 1970, of listed items (including classes of listed items) in the interests of one or more of the following:

(*a*) patient safety;

(*b*) cost-effectiveness;

(*c*) maximising appropriate use of the listed items concerned;

(*d*) appropriately applying the resources available to the Executive.

(2) Without prejudice to the generality of the Executive's power under *subsection (1)* to attach conditions to the supply or reimbursement, under section 59 of the Act of 1970, of listed items (including classes of listed items), such conditions may include one or more of the following:

(*a*) protocols for the supply of the listed items;

(*b*) the quantity of listed items which may be supplied or reimbursed, or both, during a specified period, in respect of a patient or a class of patients, or both, or in respect of patients in general;

(*c*) the period during which listed items may be supplied or reimbursed, or both;

(*d*) restrictions on the purposes for which listed items may be supplied;

(*e*) restrictions on the classes of prescribers who may prescribe the listed items;

(*f*) restrictions on the classes of patients who may be supplied with, or reimbursed under that section for, the listed items.

(3) The Executive shall, as soon as is practicable after the commencement of this section, establish and keep under review procedures designed to ensure that listed items are supplied or reimbursed, under section 59 of the Act of 1970, only if the conditions (if any) attached under this section to such supply or reimbursement, as the case may be, are complied with.

Chapter 3

Setting of relevant prices for items and listed items

Relevant prices of items and listed items.

21.—(1) Subject to *subsections (2)* and *(3)*, the relevant price, immediately before the commencement of *section 17*, of a deemed listed item shall, on and from that commencement, continue to be the relevant price of the deemed listed item.

(2) The Executive shall, when considering the proposed relevant price by the supplier of an item, take into account—

(*a*) the equivalent relevant prices (if practicably available) of the item in all other Member States where the item is marketed,

(*b*) the relevant prices of therapeutically similar listed items,

(*c*) the potential therapeutic benefits of the item for patients likely to use the item if it were to become a listed item,

(*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.

(3) Subject to *section 22*, the Executive may review and alter the relevant price of a listed item (including a deemed listed item) to take into account any change in any of the matters referred to in *subsection (2)* subsequent to the last time that the relevant price was set for those purposes.

(4) The Executive may use a competitive process to determine the relevant price of an item or a listed item.

Action to be taken by Executive where it makes decision under *section 21*.

22.—(1) The Executive shall, as soon as is practicable after making a relevant decision (but, in any case, not later than 14 days after making the relevant decision), give notice in writing of the relevant decision, together with its reasons for the relevant decision, to the supplier of the listed item the subject of the relevant decision.

(2) The Executive may, in a relevant decision, specify a date, or the occurrence of an event, from which the relevant decision shall take effect.

(3) *Part 3* of *Schedule 1* shall have effect where the Executive proposes to make a relevant decision.

(4) In this section and *Part 3* of *Schedule 1* "relevant decision" means a decision of the Executive under *section 21* to alter the relevant price of a listed item.

Chapter 4

Executive to have discretion to supply non-listed items to certain patients

Supply of items not on Reimbursement List.

23.—The Executive may, at its discretion and subject to such conditions as it considers appropriate, make arrangements to supply an item, pursuant to section 59 of the Act of 1970, to a patient notwithstanding that the item is not a listed item if the Executive is satisfied that—

(*a*) the patient requires that item for clinical reasons, and

(*b*) there is no listed item which is a suitable alternative for that item in so far as that patient is concerned.

PART 5

REFERENCE PRICING

Reference price for listed items which fall within group of interchangeable medicinal products.

24.—(1) Subject to *subsections (3)* to *(5)* and *section 25* and without prejudice to the generality of *section 21(3)*, the Executive may set a price (in this Act referred to as the "reference price") for a relevant group of interchangeable medicinal products in relation only to the listed items which fall within the group.

(2) Subject to *section 25*, the Executive shall review the reference price (if any) set for a relevant group of interchangeable medicinal products at least once a year but not more than once every 3 months and may, following any such review, set a new reference price for the relevant group of interchangeable medicinal products.

(3) The Executive shall, when setting a reference price for, or reviewing a reference price set for, a relevant group of interchangeable medicinal products take into account—

(*a*) the ability of suppliers of the relevant listed items to meet patient demand for the relevant listed items,

(*b*) the value for money afforded by the relevant listed items,

(*c*) the equivalent relevant prices (if practicably available) of the relevant listed items in all other Member States where one or more than one of the relevant listed items is marketed,

(*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.

(4) The Executive may use a competitive process to set the reference price for a relevant group of interchangeable medicinal products.

(5) Where a reference price has been set for a relevant group of interchangeable medicinal products, nothing in this section shall be construed to require the supplier of a relevant listed item to supply the relevant listed item at the reference price.

(6) When the Executive sets a reference price for a relevant group of interchangeable medicinal products, it shall, not later than 4 weeks before the reference price takes effect, give notice in writing of the reference price to community pharmacy contractors.

(7) Section 59(2) of the Act of 1970 applies to the following expenditure:

(*a*) expenditure on a relevant listed item if, and only if, the relevant listed item is priced at or below the reference price;

(*b*) expenditure on a relevant listed item which is priced above the reference price if, and only if, the medicinal product is the subject of a clinical exemption; and

(*c*) expenditure on a relevant listed item which is priced above the reference price but only up to the reference price.

Action to be taken by Executive where it makes decisions under *section 24*.

25.—(1) The Executive shall, as soon as is practicable after making a relevant decision (but, in any case, not later than 4 weeks before the relevant decision takes effect), give notice in writing of the relevant decision, together with its reasons for the relevant decision, to the suppliers of the relevant listed items which fall within the relevant group of interchangeable medicinal products the subject of the relevant decision.

(2) The Executive may, in a relevant decision, specify a date, or the occurrence of an event, from which the relevant decision shall take effect.

(3) *Part 4* of *Schedule 1* shall have effect where the Executive proposes to make a relevant decision.

(4) In this section and *Part 4* of *Schedule 1* "relevant decision" means a decision of the Executive to set a reference price for a relevant group of interchangeable medicinal products.

Reference prices and patients, etc. who decline or agree substitution.

26.—A patient, to whom a relevant scheme applies and to whom (or to a person acting on the patient's behalf) an offer referred to in *Chapter 2* of *Part 2* is made, who—

(*a*) either—

(i) does not agree to the substitution the subject of the offer, or

(ii) agrees to the substitution the subject of the offer,

and

(*b*) is dispensed the branded product or a substitute medicinal product (and notwithstanding that, in the case of an offer which falls within *section 9(2)* or *10(2)*, the pharmacist could not have dispensed the branded product),

shall, if the medicinal product so dispensed is a listed item which falls within a group of interchangeable medicinal products for which a reference price has been set and the ingredient cost of the medicinal product is higher than that reference price, be liable to pay under that relevant scheme (by whatever means, taking into account the nature of the relevant scheme and how it operates in relation to that patient) to the retail pharmacy business concerned the difference (or part thereof) between that reference price and that ingredient cost and also pay to that retail pharmacy business any other related cost arising under the relevant scheme.

PART 6

MISCELLANEOUS

Appeals to High Court against relevant decisions of Board or Executive.

27.—(1) A relevant person aggrieved by a relevant decision may, within 30 days from the date on which the relevant person was given the relevant notification, appeal to the High Court against the relevant decision.

(2) The High Court may, on the hearing of an appeal under *subsection (1)* by a relevant person—

(*a*) do any of the following:

(i) confirm the relevant decision the subject of the appeal;

(ii) cancel the relevant decision and replace it with such other decision which the relevant body could have made under this Act and which the Court considers appropriate;

(iii) remit the matter to the relevant body for further consideration,

(*b*) give the relevant body such directions as the Court considers appropriate, and

(*c*) direct how the costs of the appeal are to be borne.

(3) An appeal may not be brought from a decision of the High Court under this section except by its leave.

(4) An appeal under *subsection (1)* against a relevant decision shall not suspend the coming into operation of the relevant decision.

(5) In this section—

"relevant body", in relation to a relevant decision, means whichever of the Board or the Executive made the relevant decision;

"relevant decision" means a relevant decision within the meaning of *section 6(6)*, *19(8)*, *22(4)* or *25(4)*;

"relevant notification", in relation to the notification of a relevant person of a relevant decision, means the giving of a notice under *section 6(1)*, *19(1)*, *22(1)* or *25(1)*, as the case requires, to the relevant person of the relevant decision;

"relevant person", in relation to a relevant decision, means any person who has been notified under *section 6(1)*, *19(1)*, *22(1)* or *25(1)*, as the case requires, of the relevant decision.

Power to specify form of documents.

28.—(1) The relevant body may specify the form of documents required for the purposes of the relevant provisions of this Act as the relevant body thinks fit.

(2) The relevant body's power under *subsection (1)* may be exercised in such a way as to—

(*a*) include in the specified form of any document referred to in that subsection a statutory declaration—

(i) to be made by the person completing the form, and

(ii) as to whether the particulars contained in the form are true and correct to the best of that person's knowledge and belief,

and

(*b*) specify 2 or more forms of any document referred to in that subsection, whether as alternatives, or to provide for particular circumstances or particular cases, as the relevant body thinks fit.

(3) The form of a document specified under this section shall be—

(*a*) completed in accordance with such directions and instructions as are specified in the document,

(*b*) accompanied by such other documents as are specified in the document, and

(*c*) if the completed document is required to be provided to—

(i) the relevant body,

(ii) another person on behalf of the relevant body, or

(iii) any other person,

so provided in the manner (if any) specified in the document.

(4) In this section—

"relevant body" means—

(*a*) the Board, or

(*b*) the Executive;

"relevant provisions of this Act", in relation to a relevant body, means—

(*a*) the provisions of *Part 2* and *Part 1* of *Schedule 1* where the relevant body is the Board, and

(*b*) the provisions of this Act other than the provisions of *Part 2* and *Part 1* of *Schedule 1* where the relevant body is the Executive.

Fees.

29.—(1) The Minister for Health may, with the consent of the Minister for Public Expenditure and Reform, prescribe by regulations the fees to be paid to—

(*a*) the Board—

(i) by the authorisation holders of medicinal products, or a class of such authorisation holders, who make applications (or applications which fall within a class

of applications) under *section 5(1)* to the Board requesting the Board to add the medicinal products to a group of interchangeable medicinal products or to add a group of medicinal products to the List of Interchangeable Medicinal Products, and

(ii) in respect of the reasonable administrative costs of the Board in performing its functions under *section 5* in respect of such applications,

or

(*b*) the Executive—

(i) by the suppliers of items, or a class of such suppliers, who make applications (or applications which fall within a class of applications) under *section 18(1)* to the Executive requesting the Executive to add the items to the Reimbursement List, and

(ii) in respect of the reasonable administrative costs of the Executive in performing its functions under *section 18* in respect of such applications.

(2) Fees received by the Board or the Executive under regulations made under this section shall be paid into or disposed of for the benefit of the Exchequer in such manner as the Minister for Public Expenditure and Reform may direct.

Amendment of section 59 of Act of 1970.

30.—Section 59 of the Act of 1970 is amended—

(*a*) in subsection (1)—

(i) by substituting "Subject to *sections 20* and *23* of the *Health (Pricing and Supply of Medical Goods) Act 2013*, a" for "A", and

(ii) by inserting ", for the time being on the Reimbursement List within the meaning of *section 2(1)* of that Act," after "surgical appliances",

(*b*) in subsection (2), by inserting ", for the time being on the Reimbursement List within the meaning of *section 2(1)* of the *Health (Pricing and Supply of Medical Goods) Act 2013*," after "expenditure on drugs, medicines and medical and surgical appliances",

(*c*) in subsection (3), by inserting ", for the time being on the Reimbursement List within the meaning of *section 2(1)* of the *Health (Pricing and Supply of Medical Goods) Act 2013*," after "surgical appliances,", and

(*d*) by adding the following after subsection (4):

"(5) Nothing in this section shall be construed to affect the operation of *section 26* of the *Health (Pricing and Supply of Medical Goods) Act 2013*.".

Amendment of section 1 of Health (Miscellaneous Provisions) Act 2001.

31.—Section 1(1) of the Health (Miscellaneous Provisions) Act 2001 is amended by deleting paragraph (*b*).

Amendment of Act of 2007.

32.—The Pharmacy Act 2007 is amended—

(*a*) in section 7(1) by substituting the following for paragraph (*e*):

"(*e*) to—

(i) supervise compliance with this Act and the instruments made under it, and

(ii) supervise compliance by pharmacists with *Chapters 2* and *3* of *Part 2*, and *Part 3*, of the *Health (Pricing and Supply of Medical Goods) Act 2013*.",

(*b*) in section 18 by inserting the following after subsection (1):

"(1A) Regulations made under this section may impose duties on—

(*a*) a pharmacy owner,

(*b*) a pharmacist acting in the capacity specified in section 27(*b*), 28(*a*) or 29(*b*), and who is in personal control of the management and administration of the sale and supply of medicinal products, either where such control is exercised in respect of a single retail pharmacy business or in respect of a number of such businesses, or

(*c*) a pharmacist acting in the capacity specified in section 27(*c*), 28(*b*) or 29(*c*), who is in whole-time charge of the carrying on of the retail pharmacy business concerned,

to supervise, in the retail pharmacy business or retail pharmacy businesses in respect of which he or she is the pharmacy owner or such pharmacist, as the case may be, compliance by pharmacists with *Chapters 2* and *3* of *Part 2*, and *Part 3*, of the *Health (Pricing and Supply of Medical Goods) Act 2013*.",

and

(*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

(*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.".

Amendment of Dentists Act 1985.

33.—The Dentists Act 1985 is amended—

(*a*) in section 38(1) by substituting the following for paragraphs (*a*) and (*b*):

"(*a*) his alleged professional misconduct,

(*b*) his alleged unfitness to engage in such practice by reason of physical or mental disability, or

(*c*) his alleged failure to comply with regulations made under *section 13(2)* of the *Health (Pricing and Supply of Medical Goods) Act 2013*,",

(*b*) in section 38(3) by substituting the following for paragraph (*b*):

"(*b*) the Registrar, or any other person with the leave of the Fitness to Practise Committee, shall present to that Committee the evidence of—

(i) the alleged professional misconduct,

(ii) the alleged unfitness to practise by reason of physical or mental disability, or

(iii) the alleged failure to comply with regulations referred to in subsection (1)(*c*),

as the case may be,",

(*c*) in section 38(3)(*c*) by substituting the following for subparagraph (i) and (ii):

"(i) the alleged professional misconduct of the registered dentist,

(ii) the fitness or otherwise of that dentist to engage in the practice of dentistry by reason of his or her alleged physical or mental disability, or

(iii) the alleged failure to comply with regulations referred to in subsection (1)(*c*),",

(*d*) in section 38(5) by substituting the following for paragraphs (*a*) and (*b*):

"(*a*) guilty of professional misconduct,

(*b*) unfit to engage in the practice of dentistry because of physical or mental disability, or

(*c*) guilty of a failure to comply with regulations referred to in subsection (1)(*c*),",

and

(*e*) in section 39(1) by substituting the following for paragraph (*a*):

"(*a*) has been found by the Fitness to Practise Committee, on the basis of an inquiry and report under section 38—

(i) to be guilty of professional misconduct,

(ii) to be unfit to engage in the practice of dentistry because of physical or mental disability, or

(iii) to be guilty of a failure to comply with the regulations referred to in section 38(1)(*c*),

as the case may be, or".

Amendment of section 57 of Medical Practitioners Act 2007.

34.—Section 57(1) of the Medical Practitioners Act 2007 is amended by inserting the following after paragraph (*f*):

"(*fa*) a failure to comply with regulations made under *section 13(2)* of the *Health (Pricing and Supply of Medical Goods) Act 2013*,".

Amendment of section 55 of Nurses and Midwives Act 2011.

35.—Section 55(1) of the Nurses and Midwives Act 2011 is amended by inserting the following after paragraph (*g*):

"(*ga*) a failure to comply with regulations made under *section 13(2)* of the *Health (Pricing and Supply of Medical Goods) Act 2013*,".

Amendment of section 3 of Irish Medicines Board Act 1995.

36.—Section 3 of the Irish Medicines Board Act 1995 is amended by inserting the following after subsection (3):

"(4) The body that, immediately before the commencement of *section 36* of the *Health (Pricing and Supply of Medical Goods) Act 2013*, was known as the Irish Medicines Board shall, from such commencement, cease to be known by that name and instead be known as the Health Products Regulatory Authority.".

SCHEDULE 1

Procedural Provisions Relating to Certain Decisions of Board or Executive under this Act

PART 1

Section 6.

Decisions of Board under *section 5*

1. Subject to *paragraph 2*, where the Board proposes to make a relevant decision, it shall give notice in writing of the proposal to each person (in this Part referred to as a "relevant person") it would, if the proposal were implemented, be required under *section 6(1)* to give notice of the relevant decision.

2. A notice under *paragraph 1* shall include—

(*a*) a statement of the proposal of the Board,

(*b*) a statement setting out the reasons on which the proposal of the Board is based, and

(*c*) a statement that each relevant person has the right to make representations in writing (in this Part referred to as "relevant representations") to the Board with respect to the proposal within a period of 28 days after the relevant person concerned received the notice or such longer period as the Board permits in any particular case.

3. The Board shall, after considering the relevant representations (if any)—

(*a*) implement the proposal without modifications,

(*b*) subject to *paragraph 4*, propose modifications to the proposal, or

(*c*) decline to implement the proposal.

4. If the Board, after considering the relevant representations, wishes to propose modifications to the proposal (including any proposal to which this paragraph has previously applied), then this Part shall have effect with respect to the proposal as modified by the Board as it has effect with respect to the proposal before such modification.

PART 2

Section 19.

Decisions of Executive under *section 18*

1. Subject to *paragraph 2*, where the Executive proposes to make a relevant decision, it shall give notice in writing of the proposal to the supplier of the item or listed item the subject of the proposal.

2. A notice under *paragraph 1* shall include—

(*a*) a statement of the proposal of the Executive,

(*b*) a statement setting out the reasons on which the proposal of the Executive is based,

(*c*) a statement that the supplier of the item or the listed item the subject of the proposal has the right to make representations in writing (in this Part referred to as "relevant representations") to the Executive with respect to the proposal within a period of 28 days after the supplier received the notice or such longer period as the Executive permits in any particular case, and

(*d*) a statement that, if such supplier so wishes, he or she may give the Executive a notice in writing, within the period referred to in *subparagraph (c)*, stating that he or she will not be making any relevant representations.

3. The Executive shall, after considering the relevant representations (if any) or after being given a notice referred to in *subparagraph (d)* of *paragraph 2*—

(*a*) implement the proposal without modifications,

(*b*) subject to *paragraph 4*, propose modifications to the proposal, or

(*c*) decline to implement the proposal.

4. If the Executive, after considering the relevant representations, wishes to propose modifications to the proposal (including any proposal to which this paragraph has previously applied), then this Part shall have effect with respect to the proposal as modified by the Executive as it has effect with respect to the proposal before such modification.

Section 22.

PART 3

Decisions of Executive under *section 21*

1. Subject to *paragraph 2*, where the Executive proposes to make a relevant decision, it shall give notice in writing of the proposal to the supplier of the listed item the subject of the proposal.

2. A notice under *paragraph 2* shall include—

(*a*) a statement of the proposal of the Executive,

(*b*) a statement setting out the reasons on which the proposal of the Executive is based, and

(*c*) a statement that the supplier of the item the subject of the proposal has the right to make representations in writing (in this Part referred to as "relevant representations") to the Executive with respect to the proposal within a period of 28 days after the supplier of the listed item received the notice or such longer period as the Executive permits in any particular case.

3. The Executive shall, after considering the relevant representations (if any)—

(*a*) implement the proposal without modifications,

(*b*) subject to *paragraph 4*, propose modifications to the proposal, or

(*c*) decline to implement the proposal.

4. If the Executive, after considering the relevant representations, wishes to propose modifications to the proposal (including any proposal to which this paragraph previously applied), then this Part shall have effect with respect to the proposal as modified by the Executive as it has effect with respect to the proposal before such modification.

PART 4

Section 25.

DECISIONS OF EXECUTIVE UNDER *section 24*

1. Subject to *paragraph 2*, where the Executive proposes to make a relevant decision, it shall give notice in writing of the proposal to the suppliers of the interchangeable medicinal products which fall within the group of interchangeable medicinal products the subject of the proposal.

2. A notice under *paragraph 2* shall include—

(*a*) a statement of the proposal of the Executive,

(*b*) a statement setting out the reasons on which the proposal of the Executive is based, and

(*c*) a statement that each supplier of the interchangeable medicinal products which fall within the group of interchangeable medicinal products the subject of the proposal has the right to make representations in writing (in this Part referred to as "relevant representations") to the Executive with respect to the proposal within a period of 28 days after the supplier concerned received the notice or such longer period as the Executive permits in any particular case.

3. The Executive shall, after considering the relevant representations (if any)—

(*a*) implement the proposal without modifications,

(*b*) subject to *paragraph 4*, propose modifications to the proposal, or

(*c*) decline to implement the proposal.

4. If the Executive, after considering the relevant representations, wishes to propose modifications to the proposal (including any proposal to which this paragraph has previously applied), then this Part shall have effect with respect to the proposal as modified by the Executive as it has effect with respect to the proposal before such modification.

Section 18.

SCHEDULE 2

SUBSTITUTION OF *subsections (2)* AND *(3)* OF *section 18* WHERE *section 18(4)* OR *(5)* APPLIES

(2) Subject to this section and *section 19*, the Executive shall determine the deemed application by—

(*a*) retaining the listed item the subject of the deemed application on the Reimbursement List subject to any conditions attached to such retention in accordance with *section 20*, or

(*b*) removing the listed item the subject of the deemed application from the Reimbursement List.

(3) Where the Executive is unable to determine a deemed application under *subsection (2)* because it requires information from the supplier concerned—

(*a*) the Executive shall give notice in writing to the supplier specifying the information that it requires from the supplier in order to so determine the application, and

(*b*) if the supplier fails to give the information to the Executive within 60 days of being given the notice referred to in *paragraph (a)*, the Executive shall remove the listed item the subject of the deemed application from the Reimbursement List.

SCHEDULE 3

Section 19.

Criteria Applicable to Items and Listed Items for Purposes of Executive Making Relevant Decision under *section 18*

PART 1

Criteria Applicable to Medicinal Products

1. The medicinal product—

   (*a*) must be suitable for use under the supervision of a general medical practitioner or other relevant health professional and not be restricted to hospital or medical specialist use,

   (*b*) subject to *paragraph 2*, must not be advertised or promoted directly to the public,

   (*c*) must not be for the purpose of obtaining a cosmetic effect,

   (*d*) must be such that it is ordinarily supplied to the public only on foot of a prescription, and

   (*e*) must have a marketing authorisation referred to in *paragraph (a)* of the definition of "authorisation holder" in *section 2(1)*.

2. The Executive may disapply the criterion referred to in *paragraph 1(b)* in the case of a particular medicinal product if it is satisfied that to disapply that criterion in that case is in the interests of—

   (*a*) patient safety, or

   (*b*) public health.

PART 2

Criteria Applicable to Medical Devices, Foodstuffs for Particular Nutritional Uses and Dietary Foods for Special Medical Purposes

1. The medical device, foodstuff for a particular nutritional use or dietary food for a special medical purpose—

   (*a*) must be suitable for use under the supervision of a general medical practitioner or other relevant health professional and not be restricted to hospital or medical specialist use,

   (*b*) subject to *paragraph 2*, must not be advertised or promoted to the public, and

   (*c*) must not be for the purpose of obtaining a cosmetic effect.

2. The Executive may disapply the criterion referred to in *paragraph 1(b)* in the case of a particular medical device, foodstuff for a particular nutritional use or dietary food for a special medical purpose if it is satisfied that to disapply that criterion in that case is in the interests of—

(*a*) patient safety, or

(*b*) public health.

PART 3

General Criteria

The Executive shall have regard to—

(*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,

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

(*d*) the proposed costs, benefits and risks of the item or listed item relative to therapeutically similar items or listed items provided in other health service settings and the level of certainty in relation to the evidence of those costs, benefits and risks,

(*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,

(*h*) the efficacy (performance in trial), effectiveness (performance in real situations) and added therapeutic benefit against existing standards of treatment (how much better it treats a condition than existing therapies), and

(*i*) the resources available to the Executive.