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Medicines Act 1968

1968 c.67

An Act to make new provision with respect to medicinal products and related matters, and for purposes connected therewith. The Medicines Act 1968 does not apply in relation to veterinary medicinal products. The Medicines (Prohibition of Importation and Possession of Veterinary Drugs Order (Northern Ireland) 1977 continues in force notwithstanding, and the Medicines Act 1968 shall continue to apply in so far as is necessary for the operation of that Order

25th October 1968

Medicines Act 1968 (c.67)

Part I

Administration

1. Ministers responsible for administration of Act

(1) In this Act -

"the Ministers" means the following Ministers, that is to say, the Secretary of State and the Minister of Health and Social Services for Northern Ireland, and, in the case of anything falling to be done by the Ministers, means those Ministers acting jointly;

…..

(2) …

2. ….

2A. Establishment of the Commission on Human Medicines

(1) There shall be established a body of persons to be called the Commission on Human Medicines (referred to in this Act as "the Commission") to perform the functions assigned to the Commission by or under this Act.

(2) The Ministers shall appoint the members of the Commission.

(3) The Commission shall have at least eight members.

(4) The Ministers shall appoint the chairmen of the Expert Advisory Groups referred to in paragraphs (a) to (c) of paragraph 4(1) of Schedule 1A to this Act as members of the Commission.

(5) The Ministers shall appoint one of the members of the Commission to be chairman of the Commission

3. Functions of the Commission

(1) The Commission shall give to either or both of the Ministers advice on matters –

(a) relating to the execution of this Act,

(b) relating to the exercise of any power conferred by this Act,

(c) relating to the execution of the Marketing Authorisation Regulations, the Homeopathic Regulations, the Herbal Regulations or the Clinical Trials Regulations,

(d) relating to the exercise of any power conferred by those regulations, or

(e) otherwise relating to medicinal products,

where either the Commission consider it expedient, or they are requested by the Minister or Ministers in question, to do so.

(2) Without prejudice to the preceding subsection, and to any other duties or powers imposed or conferred on the Commission by or under this Act, the Marketing Authorisation Regulations, the Homoeopathic Regulations, the Herbal Regulations or the Clinical Trials Regulations, it shall be the duty of the Commission –

(a) to –

(i) give advice with respect to safety, quality or efficacy in relation to medicinal products,

(ii) promote the collection and investigation of information relating to adverse reactions, for the purposes of enabling such advice to be given, and

(iii) undertake the functions mentioned in section 4(4) of this Act,

except in so far as those functions are for the time being assigned to a committee established under section 4 of this Act; and

(b) to advise the licensing authority in cases where the authority –

(i) are required by the provisions of Part 2 of this Act, or by the provisions of the Marketing Authorisation Regulations, the Homoeopathic Regulations, the Herbal Regulations or the Clinical Trial Regulations, to consult the Commission with respect to any matter arising under those provisions, or

(ii) without being required to do so, elect to consult the Commission with respect to any matter arising under any of those provisions.

4. Establishment of committees.

(1) The Ministers … may by order establish one or more committees under this section.

(2) A committee may be so established for any purpose, or combination of purposes, connected with –

(a) the execution of this Act, the Marketing Authorisation Regulations, the Homoeopathic Regulations, the Herbal Regulations or Clinical Trials Regulations, or

(b) the exercise of any power conferred by this Act or those regulations,

either generally or in relation to any particular class of substances or articles to which any provision of this Act or those regulations applies.

(3) Without prejudice to the generality of subsection (2) of this section, in relation to any such class of substances or articles a committee may be established under this section for either or both of the following purposes, that is to say—

(a) giving advice with respect to safety, quality or efficacy, or with respect to all or any two of those matters;

(b) promoting the collection and investigation of information relating to adverse reactions, for the purpose of enabling such advice to be given.

(4) A committee or committees may be established under this section for the purpose of performing any function under Part VII of this Act in relation to the British Pharmacopoeia or in relation to any such compendium or list of names or other publication as is mentioned in that Part of this Act.

(4A) A committee established under this section shall have at least eight members.

(5) The Ministers … shall appoint the members of the committee, and shall appoint one of those members to be chairman of the committee.

(5A) ….

(6) In this Act "the appropriate committee", for the purposes of any provision of this Act under which a function falls to be performed, means –

(a) in a case where –

(i) a committee has been established under this section for purposes which consist of or include any of those specified in subsection (3) of this section, and

(ii) the authority performing that function considers it to be the appropriate committee in the circumstances,

that committee; and

(b) in any other case, the Commission.

5. Supplementary provisions as to Commission and committees.

(1) The provisions of Schedule 1A to this Act shall have effect with respect to the Commission, to any committee established under section 4 of this Act and to the other matters mentioned in that Schedule.

(2) The Commission shall, at such time in each year as the Ministers may direct, send to the Ministers …a report with respect to -

(a) the performance of their functions; and

(b) the performance of functions by any Expert Advisory Group appointed by them under paragraph 3 of Schedule 1A to this Act, including any Expert Advisory Group which is jointly appointed by them and another Advisory Body or Bodies,

and the Secretary of State shall lay before Parliament a copy of every such report.

(3) Each committee established under section 4 of this Act shall, at such time in each year as the Ministers may direct, send to the Ministers … a report with respect to -

(a) the performance of their functions; and

(b) the performance of functions by any Expert Advisory Group appointed by them under paragraph 3 of Schedule 1A to this Act, including any Expert Advisory Group which is jointly appointed by them and another Advisory Body or Bodies,

and the Secretary of State shall lay before Parliament a copy of every such report.

(4) Subject to the next following subsection, the Ministers, after consultation with the Commission, may by order—

(a) add to, revoke or vary any of the provisions of Schedule 1A to this Act in its application to the Commission, or

(b) confer on the Commission any new function for purposes connected with medicinal products or related matters, or

(c) terminate any function conferred on the Commission by or under this Act, or

(d) vary any such function, so however as not to confer on the Commission any new function which could not be conferred on them in accordance with paragraph (b) of this subsection.

(5) No order shall be made under this section unless a draft of the order has been laid before Parliament and approved by a resolution of each House of Parliament.

PART II

Licences and certificates relating to medicinal products

General provisions and exceptions

6. The licensing authority.

(1) For the purposes of this Part of this Act the authority responsible for the grant, renewal, variation, suspension and revocation of licences and certificates shall be a body consisting of Ministers.

(2) Any function conferred on the licensing authority by or under this Act may be performed by either of the Ministers acting alone both of them acting jointly.

(3) In accordance with the preceding provisions of this section, in this Act "the licensing authority" means either one or both of the Ministers, and, in the case of anything falling to be done by the licensing authority, means either or both of the Ministers acting as mentioned in subsection (2) of this section.

7. General provisions as to dealing with medicinal products.

(1) The following provisions of this section shall have effect subject to—

(a) any exemption conferred by or under this Part of this Act;

(b) ….; and

(c) the provisions of section 48 of this Act.

(2) Except in accordance with a licence granted for the purposes of this section (in this Act referred to as a "product licence") no person shall, in the course of a business carried on by him, and in circumstances to which this subsection applies,—

(a) sell, supply or export any medicinal product, or

(b) procure the sale, supply or exportation of any medicinal product, or

(c) procure the manufacture or assembly of any medicinal product for sale, supply or exportation.

…

(3) No person shall import any medicinal product except in accordance with a product licence.

(3A) The restrictions imposed by subsections (2) and (3) of this section shall not apply where the medicinal product concerned is an investigational medicinal product within the meaning of the Clinical Trials Regulations.

(3B) The restrictions imposed by subsections (2) and (3) of this section shall not apply where the medicinal product concerned is a homoeopathic medicinal product to which the 2001 Directive applies and which fulfils the conditions laid down in Article 14(1) of that Directive.

(4) In relation to an imported medicinal product, subsection (2) of this section applies to circumstances in which the person selling, supplying or exporting the medicinal product in question, or procuring the sale, supply or exportation or the manufacture or assembly for sale, supply or exportation of that product, has himself imported the product or procured its importation.

(5) In relation to any medicinal product which has not been imported, subsection (2) of this section applies to any circumstances in which the person selling, supplying or exporting the medicinal product in question, or procuring the sale, supply or exportation or the manufacture or assembly for sale, supply or exportation of that product,

(a) is responsible for the composition of the product, or

(b) if that product is a proprietary medicinal product, …. or an industrially produced medicinal product …, is responsible for the placing of the product on the market in the United Kingdom.

(6) For the purposes of subsection (5) of this section a person shall be taken to be responsible for the composition of a medicinal product if (but only if) in the course of a business carried on by him—

(a) he procures the manufacture of the product to his order by another person, where the order specifies, or incorporates by reference to some other document, particulars of the composition of the product ordered, whether those particulars amount to a complete specification or not, or

(b) he manufactures the product otherwise than in pursuance of an order which fulfils the conditions specified in the preceding paragraph.

(6A) … subsection (5)(b) of this section shall not apply if the product is—

(a) …

(b) a radiopharmaceutical in which the radionuclide is in the form of a sealed source, ….

(c) …

(6B) ….

(7) In this section—

…….

"homoeopathic medicinal product" means any medicinal product (which may contain a number of principles) prepared from …, substances … called homoeopathic stocks in accordance with a homoeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by any pharmacopoeia used officially in a member State;

"proprietary medicinal product" means a ready-prepared medicinal product placed on the market in the United Kingdom under a special name and in a special pack;

"radiopharmaceutical" means a medicinal product which, when ready for use, contains one or more radionuclides included for a medicinal purpose; ……

8. Provisions as to manufacture and wholesale dealing.

(1) The following provisions of this section shall have effect without prejudice to the operation of section 7 of this Act, but subject to the exemptions and provisions referred to in paragraphs (a) and (c) of subsection (1) of that section.

(2) Subject to subsection (2A) and (2C) of this section, no person shall, in the course of a business carried on by him, manufacture, assemble or import from a third country any medicinal product except in accordance with a licence granted for the purposes of this subsection (in this Act referred to as a "manufacturer's licence").

(2A) In the case of a medicinal product that is an investigational medicinal product, the restrictions imposed by subsection (2) of this section only apply –

(a) if the product has a product licence or marketing authorisation, and

(b) to the extent that the manufacture or assembly of the product is in accordance with the terms of that licence or authorisation.

(2B) In subsection (2A) of this section –

"investigational medicinal product" has the meaning given by the Clinical Trials Regulations; and

"marketing authorisation" means –

(a) a marketing authorisation issued by a competent authority in accordance with the 2001 Directive …, or

…..

(c) a marketing authorisation granted by the European Commission under Council Regulation (EEC) 2309/93.

(2C) The prohibition in subsection (2) does not apply to a person who, in connection with the importation of a medicinal product from a third country—

(a) provides facilities solely for transporting the product, or

(b) in the course of a business carried on by him as an import agent, imports the medicinal product solely to the order of another person who holds a manufacturer's licence authorising the importation of the product.

(2D) The Ministers may prescribe requirements (either generally or in relation to a prescribed class of medicinal product or activity)—

(a) with which the holder of a manufacturer's licence must comply, and

(b) which are to have effect as if they were provisions of the licence.

(3) Subject to subsection (3C) and (3D) of this section,] no person shall, in the course of a business carried on by him—

(a) sell, or offer for sale, any medicinal product by way of wholesale dealing, or

(b) distribute, otherwise than by way of sale, any proprietary medicinal product, … or industrially produced medicinal product … which has been imported, but was not consigned from a member State,

except in accordance with a wholesale dealer's licence.

(3A) Without prejudice to the generality of subsection (3) of this section but subject to subsection (3C) and (3D), no person shall, in the course of a business carried on by him, distribute by way of wholesale dealing a product to which the 2001 Directive applies apply except in accordance with a wholesale dealer's licence.

(3B) Distribution of such a product by way of wholesale dealing shall not be taken to be in accordance with a wholesale dealer's licence unless, in particular, it occurs in the course of a business which is carried on at a place or places specified in the licence.

(3C) The restrictions imposed by subsections (3) and (3A) of this section do not apply to anything done in relation to a product to which the 2001 Directive applies apply by the holder of a manufacturer's licence in respect of it.

(3D) The restrictions imposed by subsections (3) and (3A) of this section do not apply where the product concerned is an investigational medicinal product within the meaning giving by the Clinical Trials Regulations.

(3E) The Ministers may prescribe requirements (either generally or in relation to a prescribed class of medicinal product or activity)—

(a) with which the holder of a wholesale dealer's licence must comply, and

(b) which are to have effect as if they were provisions of the licence.

(4) … subsection (3)(b) of this section shall not apply if the product is—

(a) …

(b) a radiopharmaceutical in which the radionuclide is in the form of a sealed source, …..

(c) ….

(5) …

(6) In this section, … "proprietary medicinal product" and "radiopharmaceutical" … have the same meanings as in section 7 of this Act.

(7) In this section any reference to distribution of a product by way of wholesale dealing is a reference to—

(a) selling or supplying it, or

(b) procuring, holding or exporting it for the purposes of sale or supply,

to a person who receives it for the purposes of—

(i) selling or supplying it, or

(ii) administering it or causing it to be administered to one or more human beings,

in the course of a business carried on by that person.

(8) In this Act any reference to a wholesale dealer's licence is a reference to a licence granted for the purposes of subsection (3) or (3A) of this section.

9. Exemptions for doctors and dentists …..

(1) The restrictions imposed by sections 7 and 8 of this Act do not apply to anything done by a doctor or dentist which—

(a) relates to a medicinal product specially prepared, or specially imported by him or to his order, for administration to a particular patient of his, and consists of manufacturing or assembling, or procuring the manufacture or assembly of, the product, or of selling or supplying, or procuring the sale or supply of, the product to that patient or to a person under whose care that patient is, or

(b) relates to a medicinal product specially prepared at the request of another doctor or dentist, or specially imported by him or to his order at the request of another doctor or dentist, for administration to a particular patient of that other doctor or dentist, and consists of manufacturing or assembling, or procuring the manufacture or assembly of, the product, or of selling or supplying, or procuring the sale or supply of, the product to that other doctor or dentist or to that patient or to a person under whose care that patient is.

(2) …

(3) …

10. Exemptions for pharmacists.

(1) … the restrictions imposed by sections 7 and 8 of this Act do not apply to anything which is done in a registered pharmacy, a hospital, a care home service or a health centre and is done there by or under the supervision of a pharmacist and consists of—

(a) preparing or dispensing a medicinal product in accordance with a prescription given by a practitioner, or

(b) assembling a medicinal product provided that where the assembling takes place in a registered pharmacy—

(i) it shall be in a registered pharmacy at which the business in medicinal products carried on is restricted to retail sale or to supply in circumstances corresponding to retail sale and the assembling is done with a view to such sale or supply either at that registered pharmacy or at any other such registered pharmacy forming part of the same retail pharmacy business, and

(ii) the medicinal product has not been the subject of an advertisement]; and those restrictions do not apply to anything done by or under the supervision of a pharmacist which consists of procuring the preparation or dispensing of a medicinal product in accordance with a prescription given by a practitioner, or of procuring the assembly of a medicinal product.

(2) …

(3) Those restrictions do not apply to the preparation or dispensing in a registered pharmacy of a medicinal product by or under the supervision of a pharmacist in accordance with a specification furnished by the person to whom the product is or is to be sold or supplied, where—

(a) the product is prepared or dispensed for administration to that person or to a person under his care, …

(b…

(4) Without prejudice to the preceding subsections, the restrictions imposed by sections 7 and 8 of this Act do not apply to anything which is done in a registered pharmacy by or under the supervision of a pharmacist and consists of—

(a) preparing or dispensing a medicinal product for administration to a person where the pharmacist is requested by or on behalf of that person to do so in accordance with the pharmacist's own judgment as to the treatment required, and that person is present in the pharmacy at the time of the request in pursuance of which that product is prepared or dispensed, or

(b) preparing a stock of medicinal products with a view to dispensing them as mentioned in subsection (1)(a) or subsection (3) of this section or in paragraph (a) of this subsection provided that such stock is prepared with a view to retail sale or to supply in circumstances corresponding to retail sale and the preparation is done with a view to such sale or supply either at that registered pharmacy or at any other registered pharmacy forming part of the same retail pharmacy business;

and those restrictions do not apply to anything which is done in a hospital or a health centre by or under the supervision of a pharmacist and consists of preparing a stock of medicinal products with a view to dispensing them as mentioned in subsection (1)(a) of this section.

(5) Without prejudice to the preceding subsections, the restrictions imposed by section 7 of this Act do not apply to the preparation or dispensing in a registered pharmacy of a medicinal product by or under the supervision of a pharmacist where—.

(a) the medicinal product is prepared or dispensed otherwise than in pursuance of an order from any other person, and

(b) the medicinal product is prepared with a view to retail sale or supply in circumstances corresponding to retail sale at the registered pharmacy at which it is prepared, and

(c) the medicinal product has not been the subject of an advertisement.

(6) Without prejudice to the preceding subsections, the restrictions imposed by section 8(2) of this Act do not apply to anything which is done in a registered pharmacy by or under the supervision of a pharmacist and consists of preparing a medicinal product with a view to retail sale or to supply in circumstances corresponding to retail sale at that registered pharmacy.

(6A) ….

(7) Without prejudice to the preceding subsections, the restrictions imposed by section 8(3) or (3A) of this Act do not apply to anything which is done in a registered pharmacy by or under the supervision of a pharmacist and amounts to wholesale dealing, where such dealing constitutes no more than an inconsiderable part of the business carried on by the pharmacist at that pharmacy.

(7A) The … Ministers may make regulations prescribing conditions which must be complied with if a thing is to be considered for the purposes of this section as done under the supervision of a pharmacist.

(7B) Conditions prescribed under subsection (7A) may relate to supervision in the case where the pharmacist is not at the place where the thing is being done, and in that case the thing is not to be so considered if no such conditions are prescribed.

(7C) In any case, compliance with any applicable conditions is sufficient for the thing to be so considered.

(8) For the purposes of this section "advertisement" shall have the meaning assigned to it by section 92 of this Act, except that it shall not include words inscribed on the medicinal product, or on its container or package.

(9) In subsection (1) of this section, "care home service" has the meaning given by section 2(3) of the Regulation of Care (Scotland) Act 2001 (asp 8).

11. Exemption for nurses and midwives.

(1) The restrictions imposed by section 8 of this Act do not apply to the assembly of any medicinal products by a person in the course of that person's profession as a registered and qualified nurse or a registered midwife …

(2) …

12. Exemptions in respect of herbal remedies.

(1) The restrictions imposed by sections 7 and 8 of this Act do not apply to the sale, supply, manufacture or assembly of any herbal remedy in the course of a business where—

(a) the remedy is manufactured or assembled on premises of which the person carrying on the business is the occupier and which he is able to close so as to exclude the public, and

(b) the person carrying on the business sells or supplies the remedy for administration to a particular person after being requested by or on behalf of that person and in that person's presence to use his own judgment as to the treatment required.

(2) Those restrictions also do not apply to the sale, supply, manufacture or assembly of any herbal remedy where the process to which the plant or plants are subjected in producing the remedy consists only of drying, crushing or comminuting, and the remedy is, or is to be, sold or supplied—

(a) under a designation which only specifies the plant or plants and the process and does not apply any other name to the remedy, and

(b) without any written recommendation (whether by means of a labelled container or package or a leaflet or in any other way) as to the use of the remedy.

13. Exemptions for imports.

(1) The restriction imposed by section 7(3) of this Act does not apply to the importation of a medicinal product by any person for administration to himself or to any person or persons who are members of his household, and does not apply to the importation of a medicinal product where it is specially imported by or to the order of a doctor or dentist for administration to a particular patient of his.

(2) Without prejudice to the preceding subsection, the restriction imposed by section 7(3) of this Act shall not apply to the importation of a medicinal product in such circumstances as may be specified in an order made by the Ministers for the purposes of this section.

(3) Any exemption conferred by an order under this section may be conferred either in relation to medicinal products generally or in relation to a class of medicinal products specified in the order, and (in either case) may be so conferred subject to such conditions or limitations as may be so specified.

14. Exemption for re-exports.

(1) Subject to subsection (2) of this section, the restrictions imposed by sections 7 and 8 of this Act do not apply to the exportation, or the sale or offer for sale for the purposes of exportation, of any imported medicinal product if it is, or is to be, exported—

(a) in the form in which it was imported, and

(b) without being assembled in a way different from the way in which it was assembled on being imported.

(2) Section 8(3A) of this Act applies to the exportation, or the sale for exportation, of any product to which the 2001 Directive applies apply if it is, or is to be exported to an EEA State.

15. Provision for extending or modifying exemptions.

(1) The … Ministers may by order provide that sections 7 and 8 of this Act shall have effect subject to such exemptions (other than those for the time being having effect by virtue of sections 9 to 14 of this Act) as may be specified in the order.

(2) Any exemption conferred by an order under the preceding subsection may be conferred subject to such conditions or limitations as may be specified in the order.

(3) The … Ministers may by order provide that any of the provisions of sections 9 to 14 of this Act specified in the order shall cease to have effect, or shall have effect subject to such exceptions or modifications as may be so specified.

(4) No order shall be made under subsection (3) of this section unless a draft of the order has been laid before Parliament and approved by a resolution of each House of Parliament.

16. Transitional exemptions.

(1) The restrictions imposed by sections 7 and 8 of this Act do not apply to anything done before such day as the Ministers may by order appoint for the purposes of this subsection (in this Act referred to as “the first appointed day”); and, except as otherwise provided by any order made under section 17 of this Act, the following provisions of this section shall have effect in relation to things done on or after that day.

(2) Section 7(2) of this Act shall not have effect in relation to a person in respect of his selling or supplying, or procuring the sale, supply, manufacture or assembly of, medicinal products of any description if, in the course of a business carried on by him, any medicinal products of that description were sold or supplied, or procured to be sold, supplied, manufactured or assembled, at any time before the first appointed day and medicinal products of that description were effectively on the market in the United Kingdom immediately before the first appointed day, and either—

(a) information with regard to the composition of medicinal products of that description, and as to their being available for sale or supply in the United Kingdom, had before that day been made known generally to doctors, or to any particular class of doctors, or to dentists or pharmacists, or to veterinary surgeons and veterinary practitioners, in the United Kingdom, or

(b) information that the products were available for sale or supply in the United Kingdom had before that day been made known generally to the public in the United Kingdom.

(3) Section 7(3) of this Act shall not have effect in relation to a person in respect of his importing medicinal products of any description in the course of a business carried on by him if, in the course of that business, medicinal products of that description were imported within the period of twenty-four months ending with the first appointed day.

(4) Section 8(2) of this Act shall not have effect in relation to a person in respect of his manufacturing or assembling medicinal products of any description in the course of a business carried on by him if in the course of that business—

(a) medicinal products of that description were manufactured or assembled within the period of twelve months ending with the first appointed day, or

(b) medicinal products of that description were manufactured or assembled before the beginning of that period and further supplies of such products could, if required, have been manufactured or assembled within that period:

Provided that this subsection shall not have effect in relation to any particular operations carried out in the course of a business on or after the first appointed day unless the manufacture or assembly of the products as mentioned in paragraph (a) or paragraph (b) of this subsection, as the case may be, included those operations.

(5) Section 8(3) of this Act shall not have effect in relation to a person in respect of his selling or offering for sale any medicinal products by way of wholesale dealing in the course of a business carried on by him if, in the course of that business, medicinal products were being sold or offered for sale by way of wholesale dealing within the period of twelve months ending with the first appointed day.

17. Termination of transitional exemptions.

For the purposes of subsections (2) to (5) of the last preceding section, the Ministers may by one or more orders under this section appoint one or more days, subsequent to the first appointed day, and may by any such order provide that such one or more of those subsections as may be specified in that order shall cease to have effect either—

(a) generally in relation to anything done on or after the day appointed by that order, or

(b) in relation to anything done on or after that day in so far as it consists of operations or activities, or relates to medicinal products of any such class, as may be so specified.

Applications for, and grant and renewal of, licences

18. Application for licence.

(1) Any application for the grant of a licence under this Part of this Act shall be made to the licensing authority and shall be made in such form and manner, and shall contain, or be accompanied by, such information, documents, samples and other material, as may be prescribed.

(2) Any such application shall indicate the descriptions of medicinal products in respect of which the licence is required, either by specifying the descriptions of medicinal products in question or by way of an appropriate general classification.

(3) ...

19. Factors relevant to determination of application for licence.

(1) Subject to the following provisions of this Part of this Act, in dealing with an application for a product licence the licensing authority shall in particular take into consideration—

(a) the safety of medicinal products of each description to which the application relates;

(b) the efficacy of medicinal products of each such description for the purposes for which the products are proposed to be administered; and

(c) the quality of medicinal products of each such description, according to the specification and the method or proposed method of manufacture of the products, and the provisions proposed for securing that the products as sold or supplied will be of that quality.

(2) In taking into consideration the efficacy for a particular purpose of medicinal products of a description to which such an application relates, the licensing authority shall leave out of account any question whether medicinal products of another description would or might be equally or more efficacious for that purpose:

Provided that nothing in this subsection shall be construed as requiring the licensing authority, in considering the safety of medicinal products of a particular description, in relation to a purpose for which they are proposed to be administered, to leave out of account any question whether medicinal products of another description, being equally or more efficacious for that purpose, would or might be safer in relation to that purpose.

(3) Where any such application indicates that the purposes for which the licence is required relate (wholly or partly) to medicinal products which have been or are to be imported, then in dealing with the application, in so far as it relates to such products, the licensing authority shall also take into consideration in particular the methods, standards and conditions of manufacture of those products and may, if they think fit, require the production by the applicant of any one or more of the following, that is to say—

(a) an undertaking, given by the manufacturer of any such products, to permit the premises where they are or are to be manufactured, and the operations carried on or to be carried on in the course of manufacturing them, to be inspected by or on behalf of the licensing authority;

(b) an undertaking, given by or on behalf of the manufacturer of any such products, to comply with any prescribed conditions or any conditions attached to the licence by the licensing authority;

(c) a declaration, given by or on behalf of the manufacturer of any such products, that, in relation to the manufacture of those products, any requirements imposed by or under the law of the country in which they are or are to be manufactured have been or will be complied with.

(4) Where any such application indicates that the purposes for which the license is required relate exclusively to the exportation of medicinal products, the licensing authority shall leave out of account considerations of safety and efficacy (as mentioned in paragraphs (a) and (b) of subsection (1) of this section) if satisfied that in the circumstances it is reasonable to do so.

(5) In dealing with an application for a manufacturer's licence the licensing authority shall in particular take into consideration—

(a) the operations proposed to be carried out in pursuance of the licence:

(b) the premises in which those operations are to be carried out;

(c) the equipment which is or will be available on those premises for carrying out those operations;

(d) the qualifications of the persons under whose supervision those operations will be carried out; and

(e) the arrangements made or to be made for securing the safekeeping of, and the maintenance of adequate records in respect of, medicinal products manufactured or assembled in pursuance of the licence.

(6) In dealing with an application for a wholesale dealer's licence the licensing authority shall in particular take into consideration—

(a) the premises on which medicinal products of the descriptions to which the application relates will be stored;

(b) the equipment which is or will be available for storing medicinal products on those premises;

(c) the equipment and facilities which are or will be available for distributing medicinal products from those premises; and

(d) the arrangements made or to be made for securing the safekeeping of, and the maintenance of adequate records in respect of, medicinal products stored on or distributed from those premises.

(7) The preceding provisions of this section shall have effect subject to the provisions of this Part of this Act relating to licences of right.

20. Grant or refusal of licence.

(1) Subject to sections 8(2E) and (3E) and 19, and to the following provisions of this Act, on any application to the licensing authority for a licence under this Part of this Act the licensing authority—

(a) may grant a licence containing such provisions as they consider appropriate, or

(b) if, having regard to the provisions of this Act and any Community obligation, they consider it necessary or expedient to do so, may refuse to grant a licence.

(1A) The licensing authority must either grant or refuse any application for a licence under this Part, before the end of a period of 90 days from the date upon which they receive the application.

(1B) If there are requirements in force under section 18 that apply to the application, subsection (1A) applies only if the requirements have been met.

(1C) If a notice under section 44 requires the applicant to provide the licensing authority with information, the period specified in subsection (1) stops running when the notice is given, and does not start running again until—

(a) the licensing authority receives the information; or

(b) the applicant has shown to the reasonable satisfaction of the licensing authority why he is unable to provide it.

(2) The licensing authority shall not refuse to grant such a licence on any grounds relating to the price of any product, and shall not insert in any such licence any provisions as to the price at which any product may be sold, supplied, imported or exported.

(3) The licensing authority shall not refuse to grant such a licence on any grounds relating to the safety, quality or efficacy of medicinal products of any description, except after consultation with the appropriate committee ...

(4) …

(5) Where on an application for a licence under this Part of this Act—

(a) the licensing authority refuse to grant a licence, or

(b) the licensing authority grant a licence otherwise than in accordance with the application, and the applicant requests the licensing authority to state their reasons,

the licensing authority shall serve on the applicant a notice stating the reasons for their decision.

21. Procedure on reference to appropriate committee.

(1) Where the appropriate committee are consulted under section 20(3) of this Act and are of the provisional opinion that, on grounds relating to safety, quality or efficacy, they -

(a) may be unable to advise the licensing authority to grant the licence; or

(b) may be unable to advise the licensing authority to grant it unless it contains provisions otherwise than in accordance with the application,

they shall notify the applicant accordingly.

(2) A person who has been so notified may, within the time allowed, give notice of his wish to make written or oral representations to the appropriate committee.

(3) The appropriate committee shall give the applicant an opportunity to make such representations in accordance with subsections (4) to (7) of this section.

(4) Subject to subsection (5) of this section, the applicant shall provide the appropriate committee with -

(a) his written representations or a written summary of the oral representations he intends to make; and

(b) any documents on which he wishes to rely in support of those representations,

before the end of the period of six months beginning with the date of the notice referred to in subsection (2) of this section, or within such shorter period as the appropriate committee may specify in the notification under subsection (1).

(5) If the applicant so requests, the appropriate committee may extend the time limit referred to in subsection (4) of this section, up to a maximum period of twelve months beginning with the date of the notice referred to in subsection (2) of this section.

(6) The applicant may not submit any additional written representations or documents once the time limit referred to in subsections (4) and (5) of this section has expired, except with the permission of the appropriate committee.

(7) If the applicant gave notice of his wish to make oral representations, the appropriate committee shall, after receiving a written summary and any other documents in accordance with subsection (4) of this section, arrange for the applicant to make such representations at a hearing before the committee.

(8) The appropriate committee shall -

(a) take into account such representations as are made in accordance with this section; and

(b) report their findings and advice to the licensing authority, together with the reasons for their advice.

(9) After receiving the report of the appropriate committee, the licensing authority shall -

(a) decide whether to grant or refuse the application, or to grant it otherwise than in accordance with the application; and

(b) take the report into account when making their decision.

(10) The licensing authority shall notify the applicant of -

(a) the decision made pursuant to subsection (9) of this section; and

(b) the advice given to them by the appropriate committee and the reasons for that advice.

(11) If -

(a) the applicant has made written representations prior to 30th October 2005 and the licensing authority have notified the applicant of the authority's decision to refuse to grant the licence, or to grant it otherwise than in accordance with the application; or

(b) the applicant has not made written representations prior to 30th October 2005 and the licensing authority have notified the applicant of the authority's decision to refuse to grant the licence, or to grant it otherwise than in accordance with the application, on grounds which differ from those relied on in the advice of the appropriate committee,

the applicant may, within the time allowed, notify the licensing authority that he wishes to appear before and be heard by a person appointed by the licensing authority with respect to the decision.

(12) In this Part of the Act, “the time allowed” means the period of twenty-eight days beginning with the date of the relevant notification, or such longer period as the licensing authority may allow in any particular case

22. Procedure in other cases.

(1) This section applies when -

(a) an application is made for the grant of a licence under this Part of this Act; and

(b) the appropriate committee –

(i) is not consulted under subsection (3) of section 20, or

(ii) is consulted under that subsection but does not give a provisional opinion in accordance with section 21(1).

(2) If the licensing authority propose -

(a) to refuse to grant the licence, or

(b) to grant it otherwise than in accordance with the application,

they shall notify the applicant of their proposals and the reasons for them.

(3) If the applicant is so notified, he may, within the time allowed -

(a) notify the licensing authority of his wish to appear before and be heard by a person appointed by the licensing authority with respect to the proposal; or

(b) make representations in writing to the licensing authority with respect to the proposal referred to in the notification.

(4) If the applicant makes written representations in accordance with subsection (3)(b) of this section, the licensing authority shall take those representations into account before determining the application.

22A. Hearing before person appointed

(1) If the applicant gives notice under section 21(11) or section 22(3) of his wish to appear before and be heard by a person appointed by the licensing authority, the authority shall -

(a) make that appointment; and

(b) arrange for the applicant to have an opportunity of appearing before that person.

(2) The person appointed –

(a) shall not be, or at any time have been, a member of –

(i) the Commission on Human Medicines or any of its Expert Advisory Groups,

(ii) the Medicines Commission formerly established under section 2 of this Act or any of its committees, or

(iii) a committee established under section 4 of this Act, or any sub-committee of such a committee; and

(b) shall not be an officer or servant of any Minister of the Crown.

(3) Subject to subsection (4) of this section, the applicant shall provide the person appointed with -

(a) a written summary of the oral representations he intends to make; and

(b) any documents on which he wishes to rely in support of those representations,

before the end of the period of three months beginning with the date of the notice referred to in subsection (1) of this section.

(4) If the applicant so requests, the person appointed may, after consulting the licensing authority, extend the time limit referred to in subsection (3) of this section, up to a maximum period of six months beginning with the date of the notice referred to in subsection (1) of this section.

(5) If the applicant fails to comply with the time limit in subsection (3) of this section, or, where he has been granted an extended time limit under subsection (4) of this section, that time limit –

(a) he may not appear before or be heard by the person appointed, and

(b) the licensing authority shall decide whether to grant or refuse the licence, or to grant it otherwise than in accordance with the application, and notify the applicant accordingly.

(6) The applicant may not submit any additional written representations or documents once the time limit has expired, except with the permission of the person appointed.

(7) At the hearing before the person appointed, both the applicant and the licensing authority may make representations.

(8) If the applicant so requests the hearing shall be in public.

(9) After the hearing –

(a) the person appointed shall provide a report to the licensing authority; and

(b) the licensing authority shall take the report into account and decide whether to grant or refuse the licence, or to grant it otherwise than in accordance with the application, or to confirm or alter their decision, as the case may be.

(10) The licensing authority shall then -

(a) notify the applicant of their decision;

(b) if the applicant so requests, provide the applicant with a copy of the report of the person appointed.

23. Special provisions as to effect of manufacturer's licence.

(1) Subject to … the following provisions of this section, a manufacturer's licence shall not have effect so as to authorise the manufacture or assembly of medicinal products of any description for sale or supply to any other person, or for exportation, unless either—

(a) the holder of the licence is also the holder of a product licence or traditional herbal registration which is applicable to medicinal products of that description, or

(b) the products are manufactured or assembled to the order of –

(i) a person who is the holder of such a product licence or traditional herbal registration, or

(ii) if the products are to be used for the purposes of a clinical trial, the sponsor of that trial,

and (in either case) the products are manufactured or assembled in accordance with that product licence or traditional herbal registration.

(2) … the preceding subsection shall not have effect in relation to the manufacture or assembly of any medicinal product to the order of a practitioner, where the practitioner—

(a) being a doctor or dentist, states that the product is required for administration to a patient of his or is required, at the request of another doctor or dentist, for administration to a patient of that other doctor or dentist, ..

(b) …

and shall not have effect in relation to the manufacture or assembly of any medicinal product to the order of a pharmacist in accordance with a prescription given by a practitioner.

(3) …

(4) If by virtue of an order made under section 15 of this Act an exemption is conferred in respect of the restrictions imposed by section 7 of this Act, but no corresponding exemption is conferred in respect of the restrictions imposed by section 8(2) of this Act, the order may provide that subsection (1) of this section shall have effect subject to such exceptions or modifications as the Ministers consider appropriate in the circumstances.

(5) Where subsection (1) of this section has effect in relation to medicinal products of any description, and the conditions specified in that subsection are not fulfilled, the manufacture or assembly of medicinal products of that description for sale or supply to another person, or for exportation, notwithstanding that it complies with the provisions contained in the manufacturer's licence, shall for the purposes of this Act be deemed to be not in accordance with that licence.

(6) In this section, "clinical trial" and "sponsor", in relation to a clinical trial, have the meaning given by the Clinical Trials Regulations.

24. Duration and renewal of licence.

(1) Subject to the following provisions of this section, every licence granted under this Part of this Act, unless previously renewed or revoked, shall expire at the end of the period of five years from the date on which it was granted or the date as from which it was last renewed, as the case may be, or at the end of such shorter period from that date as may be specified in the licence as granted or last renewed.

(1A) Where any licence has been granted under this Part of this Act and the licensing authority subsequently consider that it would no longer be possible to grant that licence without contravening a Community obligation (other than an obligation under Title V of the 2001 Directive), the licence shall (notwithstanding subsection (1) above) expire on such date as may be specified in a notice served on the holder of the licence by the licence authority.

(2) Any licence granted under this Part of this Act, if it has not been revoked, may, on the application of the holder of the licence, be renewed by the licensing authority for a further period of five years from the date on which it would otherwise expire or such shorter period from that date as the licensing authority may determine.

(3) On an application to the licensing authority for the renewal of a licence under this Part of this Act, the licensing authority—

(a) may renew the licence, with or without modifications, for such a further period as is mentioned in subsection (2) of this section, or

(b) may grant to the applicant a new licence containing such provisions as the licensing authority consider appropriate, or

(c) if, having regard to the provisions of this Act [F58and any Community obligation under [F59the 2001 Directive other than Titles VI, VII and VIII of that Directive]], they consider it necessary or expedient to do so, may refuse to renew the licence or to grant a new licence.

(4) In relation to any such application the provisions of sections 18 and 19, subsections (2) to (5) of section 20 and sections 21 to 22A of this Act shall have effect as if in those provisions any reference to refusing a licence included a reference to refusing to renew a licence and any reference to granting a licence included a reference to renewing it.

(5) Every application for the grant or renewal of a licence under this Part of this Act shall, unless it otherwise expressly provides, be taken to be an application for the grant or renewal of the licence for the full period of five years mentioned in subsection (1) or subsection (2) of this section, as the case may be; and in this Part of this Act any reference (including a reference implied by virtue of the last preceding subsection) to the grant or renewal of a licence otherwise than in accordance with the application shall be construed accordingly.

(6) Where an application for the renewal of a licence under this Act has been duly made—

(a) the licence shall not cease to be in force by virtue of the preceding provisions of this section before the licensing authority have determined the application, and

(b) if by an interim order made under section 107(3)(a) of this Act the operation of the decision of the licensing authority on the application is suspended, the licence shall not cease to be in force by virtue of those provisions so long as the operation of the decision continues to be suspended by the order.

(7) . . .

Licences of right

25. Entitlement to licence of right.

(1) Where any of the provisions of subsections (2) to (5) of section 16 of this Act has effect in relation to a person, he may, before such date as may be appointed for the purposes of this section by an order made by the Ministers, make an application in accordance with section 18 of this Act, stating that it is an application for a licence of right.

(2) On any such application made as mentioned in the preceding subsection the applicant, on proving that any of the provisions of subsections (2) to (5) of section 16 of this Act has effect in relation to him, shall be entitled to the grant of a licence under this Part of this Act in accordance with the next following section.

(3) In this section and in sections 26 and 27 of this Act any reference to proof is a reference to proof to the reasonable satisfaction of the licensing authority.

(4) In this Act "licence of right" means a licence to which a person is entitled by virtue of this section, including such a licence which has been renewed (with or without modifications) but not a licence granted instead of the renewal of such a licence.

26. Scope of licence of right in different cases.

(1) Where a person is entitled to the grant of a licence of right by reason that subsection (2) or subsection (3) of section 16 of this Act has effect in relation to him, he shall be entitled to the grant of a product licence; but, subject to the following provisions of this section,—

(a) the licence shall be granted so as not to extend to medicinal products of any description other than those in respect of which the conditions specified in the subsection in question are proved to have been fulfilled, and

(b) where the conditions specified in subsection (3) (but not those specified in subsection (2)) of that section are proved to have been fulfilled, then, without prejudice to the preceding paragraph, the licence granted shall be limited to the importation of medicinal products.

(2) Where a person is entitled to the grant of a licence of right by reason that subsection (4) of section 16 of this Act has effect in relation to him, he shall be entitled to the grant of a manufacturer's licence; but, subject to the following provisions of this section, the licence shall be granted so as not to extend—

(a) to medicinal products of any description, unless it is proved that medicinal products of that description were being manufactured or assembled in the course of the business in question during the period mentioned in that subsection, or

(b) to operations of any kind other than those in relation to which that subsection has been proved to have effect.

(3) Where a person is entitled to the grant of a licence of right by reason that subsection (5) of section 16 of this Act has effect in relation to him, he shall be entitled to the grant of a wholesale dealer's licence.

(4) A licence of right granted in accordance with subsection (1) or subsection (2) of this section shall (without prejudice to either of those subsections) be granted subject to such provisions as appear to the licensing authority to be requisite for securing that the specification of medicinal products of any description to which the licence relates, and the purposes for which any such products are authorised by the licence to be sold, supplied, exported, imported, manufactured or assembled, will be in accordance with those stated in the application for the licence.

(5) Where a licence of right—

(a) is granted in accordance with subsection (1) or subsection (2) of this section in circumstances where, immediately before the first appointed day, the manufacture of medicinal products of any description to which the licence relates was authorised by a licence issued under Part I of the Therapeutic Substances Act 1956 or under Part II of the Diseases of Animals Act 1950 or of the Diseases of Animals Act (Northern Ireland) 1958, or

(b) is granted in accordance with subsection (1) of this section in circumstances where, immediately before the first appointed day, the importation of medicinal products of any such description was authorised by a licence so issued,

the provisions of the licence so issued, and the provisions of any regulations made under Part I of the Therapeutic Substances Act 1956 or (as the case may be) of any order made under Part II of the said Act of 1950 or of the said Act of 1958, in so far as immediately before that day they were applicable to medicinal products of that description, shall be deemed to be incorporated in the licence of right granted under this Act, in its application to medicinal products of that description, and shall have effect accordingly as provisions of the licence of right until it expires or is renewed.

(6) A breach of any requirement imposed by this section in respect of the grant of a licence shall not invalidate the licence; and, except as provided by section 107 of this Act, the duty of the licensing authority to comply with any such requirement shall not be enforceable by any legal proceedings.

27. Proceedings on application for licence of right.

(1) Sections 19 to 22A of this Act shall not have effect in relation to any application for a licence of right.

(2) If on any such application the licensing authority—

(a) propose to refuse to grant a licence on that application, on the grounds that none of the provisions of subsections (2) to (5) of section 16 of this Act has been proved to have effect in relation to the applicant, or

(b) propose to grant a licence which will not extend to some of the matters specified in the application.

the licensing authority shall, before the end of the period of three months from the date on which the application is received by them, serve on the applicant a notice stating their proposals and the reasons for them and, in a case falling within paragraph (b) of this subsection, the matters specified in the application to which it is proposed that the licence should not extend.

(3) If, within the time allowed after the service of a notice under subsection (2) of this section, the applicant gives notice to the licensing authority of his desire to be heard under this subsection or makes representations in writing to the licensing authority with respect to their proposals, then, before determining the application, the licensing authority shall afford to him an opportunity of appearing before, and being heard by, a person appointed for the purpose by the licensing authority, or shall take those representations into account, as the case may be.

(4) Where the applicant avails himself of the opportunity afforded to him in pursuance of subsection (3) of this section or makes representations in writing as mentioned in that subsection, then if—

(a) the licensing authority refuse to grant a licence on the application, or

(b) grant a licence otherwise than in accordance with the application, and the applicant requests the licensing authority to state their reasons.

the licensing authority shall serve on the applicant a notice stating the reasons for their decision.

(5) If, in a case where the licensing authority have served a notice under subsection (2) of this section, the application is not finally disposed of before the date which, in relation to any matters specified in the application, is the relevant date, then on and after that date, and until the application has been finally disposed of, the provisions of this Act shall have effect in relation to those matters as if the licensing authority had granted a licence of right in accordance with the application.

(6) Where, on an application for a licence of right, the licensing authority do not serve a notice under subsection (2) of this section before the end of the period mentioned in that subsection, the licensing authority shall be required to grant a licence in accordance with sections 25 and 26 of this Act as if all the matters specified in the application had been proved; and if such a licence has not been granted before the date which, in relation to any of those matters, is the relevant date, the provisions of this Act shall have effect on and after that date in relation to those matters as if the licensing authority had granted a licence of right in accordance with the application.

(7) For the purposes of this section the relevant date, in relation to any matters specified in an application, is the date on which, in accordance with one or more orders made under section 17 of this Act, that subsection of section 16 of this Act which has effect in relation to those matters ceases to have effect in relation to them; and an application shall for the purposes of this section be taken to be finally disposed of on (but not before) the occurrence of whichever of the following events last occurs, that is to say—

(a) the licensing authority make a decision determining the application;

(b) the time within which an application under section 107 of this Act with respect to that decision can be made expires without its having been made;

(c) if such an application under section 107 of this Act is made, the proceedings on the application under that section are finally determined or abandoned or otherwise disposed of;

(d) if there is an appeal against the decision in any such proceedings as are mentioned in paragraph (c) of this subsection, or an appeal against the decision on such an appeal, the proceedings on that appeal are finally determined or abandoned or otherwise disposed of;

(e) the time for bringing any such appeal as is mentioned in paragraph (d) of this subsection expires without its having been brought.

(8) Subsections (2), (8) and (10)(b) of section 22A of this Act shall have effect in relation to a person appointed under subsection (3) of this section and to proceedings before him and his report as they have effect for the purposes of that section.

Suspension, revocation and variation of licences

28. General power to suspend, revoke or vary licences.

(1) Subject to the following provisions of this Part of this Act, the licensing authority may suspend a licence under this Part of this Act for such period as the authority may determine, or may revoke, or vary the provisions of, any such licence.

(2) The suspension or revocation of a licence under this section may be total or may be limited to medicinal products of one or more descriptions or to medicinal products manufactured, assembled or stored on any particular premises or in a particular part of any premises.

(3) Subject to subsection (3A) of this section, the powers conferred by this section shall not be exercisable by the licensing authority in relation to a product licence except on one or more of the following grounds, that is to say—

(a) that the matters stated in the application on which the licence was granted were false or incomplete in a material particular;

(b) that any of the provisions of the licence has to a material extent been contravened by the holder of the licence or by a person procured by him to manufacture or assemble medicinal products of a description to which the licence relates;

(c) that medicinal products of any such description, as sold, supplied, exported, imported, manufactured or assembled in pursuance of the licence, fail to a material extent to correspond to the characteristics by reference to which the licence was granted;

(d) that the holder of the licence has without reasonable excuse failed to comply with a requirement imposed on him under section 44(2) of this Act to furnish information to the licensing authority with respect to medicinal products of any such description;

(e) that any premises on which, or in part of which, medicinal products of any such description are manufactured, assembled or stored by or on behalf of the holder of the licence are unsuitable;

(f) in the case of a licence other than a licence of right, that the holder of the licence has not, within two years after the grant of the licence, notified to the licensing authority, in relation to each description of medicinal products to which the licence relates, a date on which medicinal products of that description were effectively on the market in the United Kingdom;

(g) that medicinal products of any description to which the licence relates can no longer be regarded as products which can safely be administered for the purposes indicated in the licence, or can no longer be regarded as efficacious for those purposes;

(h) that the specification and standards to which medicinal products of any such description are manufactured can no longer be regarded as satisfactory.

(i) ...

(j) that, in relation to medicinal products of any description to which the licence relates (other than products to which the 2001 Directive applies) any of the provisions contained in regulations which—

(i) are made under section 85 of this Act (labelling and marking of containers and packages), and

(ii) impose requirements which give effect to Community obligations,

has to a material extent been contravened by the holder of the licence or by a person procured by him to manufacture or assemble such medicinal products.

(3A) Where a product licence relates to a product to which the 2001 Directive applies, the power conferred by this section to suspend a licence shall be exercisable in relation to the licence on the ground that—

(a) any of the provisions contained in regulations made under section 85 (labelling and marking of containers and packages) or 86 (leaflets) of this Act, or

(b) section 86(4),

has to a material extent been contravened in relation to the product by the holder of the licence or by a person procured by him to manufacture or assemble the product.

(4) Subject to the following provisions of this section, the powers conferred by this section shall not be exercisable in relation to a manufacturer's licence or a wholesale dealer's licence except on one or more of the following grounds, that is to say—

(a) that the matters stated in the application on which the licence was granted were false or incomplete in a material particular;

(b) that a material change of circumstances has occurred in relation to any of those matters;

(c) that any of the provisions of the licence has to a material extent been contravened by the holder of the licence;

(d) that the holder of the licence has without reasonable excuse failed to comply with a requirement imposed on him under section 44(2) of this Act to furnish information to the licensing authority with respect to medicinal products of a description to which the licence relates.

(5) In relation to a manufacturer's licence, the powers conferred by this section shall be exercisable on either of the following grounds, in addition to those specified in subsection (4) of this section, that is to say—

(a) that the holder of the manufacturer's licence has carried out processes of manufacture or assembly to the order of another person who is the holder of a product licence, and has habitually failed to comply with the provisions of that product licence;

(b) that the holder of the manufacturer's licence does not have the requisite facilities for carrying out properly processes of manufacture or assembly authorised by the licence.

(6) In relation to a wholesale dealer's licence, the powers conferred by this section shall be exercisable on the following grounds, in addition to those specified in subsection (4) of this section, that is to say, that the equipment and facilities for storing or distributing medicinal products which are available to the holder of the licence are inadequate to maintain the quality of medicinal products of one or more descriptions to which the application for the licence related.

(7) The preceding provisions of this section shall have effect subject to the next following section.

29. Procedure where licensing authority propose to suspend, revoke or vary licence under s. 28.

(1) The provisions of Schedule 2 to this Act shall have effect where the licensing authority propose to exercise any power conferred by section 28 of this Act.

(2) Without prejudice to any requirement of that Schedule as to the service of notices, where in the exercise of any such power the licensing authority suspend, revoke or vary a licence, they shall serve on the holder of the licence a notice giving particulars of the suspension, revocation or variation and of the reasons for their decision to suspend, revoke or vary the licence.

30. Variation of licence on application of holder.

Without prejudice to any power exercisable by virtue of section 28 of this Act, the licensing authority may, on the application of the holder of a licence under this Part of this Act, vary the provisions of the licence in accordance with any proposals contained in the application, if they are satisfied that the variation will not adversely affect the safety, quality or efficacy of medicinal products of any description to which the licence relates.

Clinical trials and medicinal tests on animals

31. ……

32. …

33. ...

34. ...

35. ...

36. ...

37. Transitional provisions as to clinical trials and medicinal tests on animals.

(1) The provisions of sections …. 32, 34 and 36 of this Act shall have effect subject to the following provisions of this section.

(2) The restrictions imposed by section …. 32 of this Act do not apply to anything done before the first appointed day, and the restrictions imposed by section 34 of this Act do not apply where the substance or article in question was administered before that day.

(3) Where, in the course of a series of investigations carried out during a period ending on the first appointed day,—

(a) …

(b) substances or articles have been administered by way of a medicinal test on animals,

the restrictions imposed by section …. 32 of the Act do not apply to anything done …. in relation to similar substances or articles for the purpose of continuing that series of investigations, if it is done on or after the first appointed day but before such date as may be appointed for the purposes of this section by an order made by the Ministers.

(4) If, on an application for …. an animal test certificate which is made before the date appointed for the purposes of this section, it is proved to the reasonable satisfaction of the licensing authority that—

(a) Substances or articles specified in the application were administered by way of a medicinal test on animals in the course of a series of investigations as mentioned in subsection (3) of this section, and

(b) that series of investigations was in progress immediately before the first appointed day, and

(c) the certificate is required for the purpose of continuing the series,

the applicant shall be entitled to the issue of a certificate such as will enable the series to be continued and completed within a reasonable time after the date appointed for the purposes of this section.

(5) Section 36(3) of this Act shall not have effect in relation to any application for a certificate as being a certificate to which the applicant is entitled by virtue of subsection (4) of this section; but the provisions of section 27 of this Act shall have effect in relation to any such application, as if—

(a) any reference in that section to a licence of right were a reference to such a certificate;

(b) for the reference in subsection (2)(a) of that section to the grounds of refusal therein mentioned there were substituted a reference to the grounds that the conditions specified in subsection (4) of this section have not been fulfilled in relation to the application; and

(c) in subsection (6) of that section the reference to sections 25 and 26 of this Act were a reference to subsection (4) of this section;

and for the purposes of the application of those provisions in accordance with this subsection the relevant date, in relation to any matters specified in the application, shall be the date appointed for the purposes of this section.

38. ...

39. ...

40. ...

41. …

42. …

Supplementary provisions

43. Extension of s. 7 to certain special circumstances.

(1) Where in the course of a business carried on by him a person sells, supplies or exports a substance or article for use wholly or mainly in either or both of the ways specified in section 130(1) of this Act, and the substance or article, not having been—

(a) manufactured or imported for such use, or

(b) previously sold or supplied for such use,

does not constitute a medicinal product before that person so sells, supplies or exports it, then (subject to subsection (2) of this section) subsection (2) of section 7 of this Act, if apart from this subsection it would not so have effect, shall have effect in relation to the sale, supply or exportation of the substance or article as if he were selling, supplying or exporting it in circumstances to which that subsection applies.

(2) Subsection (1) of this section shall not have effect in relation to a transaction whereby a person, in the course of a business carried on by him, sells a substance or article by retail or supplies a substance or article in circumstances corresponding to retail sale unless in the course of that business the substance or article has been assembled for the purpose of being sold or supplied by him.

(3) In any reference in this Part of this Act to the provisions of, or the restrictions imposed by, section 7 of this Act, the reference to that section shall be construed as including a reference to subsection (2) of that section as extended by the preceding subsections.

(4) Where in the course of a business carried on by him a person proposes to sell, supply or export a substance or article for use as mentioned in subsection (1) of this section, where the substance or article will not constitute a medicinal product before he so sells, supplies or exports it and he will not be selling, supplying or exporting it in circumstances to which section 7(2) of this Act applies, he may, if he so desires, apply for a product licence in respect of that substance or article, and the licensing authority (subject to the provisions of sections 19 to 22A of this Act) may grant to him a product licence in respect of it, as if he were proposing to sell, supply or export it in circumstances to which section 7(2) of this Act applies; and a product licence so granted may be renewed, suspended, revoked or varied accordingly.

(5) In subsection (2) of this section the reference to assembling a substance or article in the course of a business carried on by a person is a reference to doing in the course of that business anything which (in accordance with section 132(1) of this Act) would constitute assembling if it had been a medicinal product when sold or supplied to him.

44. Provision of information to licensing authority.

(1) Where an application has been made to the licensing authority for a licence under this Part of this Act (including a licence of right) ..the licensing authority, before determining the application, may request the applicant to furnish to the licensing authority such information

relating to the application as the licensing authority may consider requisite; and, where any such request has been made, the licensing authority shall not be required to determine the application until either—

(a) the information requested has been furnished to them, or

(b) it has been shown to their reasonable satisfaction that the applicant is unable to furnish the information.

(2) The licensing authority may serve on the holder of a licence under this Part of this Act…, a notice requiring him, within such time as may be specified in the notice, to furnish to the licensing authority information of any description specified in the notice in accordance with the following provisions of this section.

(3) Except as provided by subsection (4) of this section, a notice under subsection (2) of this section shall not be served unless it appears to the licensing authority, or it is represented to them … by the appropriate committee, that circumstances exist by reason of which it is necessary to consider whether the licence … should be varied, suspended or revoked; and the information required by such a notice shall be such as appears to the licensing authority, or is represented to them … by the committee, to be requisite for considering that question.

(4) Subsection (3) of this section shall not have effect in the case of a licence of right, …, whether the licence … has been renewed or not; and, in the case of such a licence …, a notice under this section may be served at any time and may require any information which, in the opinion of the licensing authority, would be relevant if—

(a) section 25 …of this Act had not been enacted, and

(b) the licensing authority were then dealing with an application, by the person who is the holder of the licence or certificate, for the grant … of a licence or certificate containing the same provisions as those contained in the licence or certificate in question.

(5) Before the end of the period of two years from the date on which a product licence, other than a licence of right, is granted, the holder of the licence shall, in respect of each description of medicinal products to which the licence relates which is effectively on the market in the United Kingdom within that period, notify to the licensing authority a date on which medicinal products of that description were effectively on that market.

45. Offences under Part II.

(1) Subject to the next following section, any person who contravenes any of the provisions of section 7, section 8, … of this Act, or who is in possession of any medicinal pro4duct … for the purpose of selling, supplying or exporting it in contravention of either of those sections, shall be guilty of an offence.

(2) Where any medicinal product … is imported in contravention of section 7, … of this Act, any person who, otherwise than for the purpose of performing or exercising a duty or power imposed or conferred by or under this Act or any other enactment, is in possession of the product … knowing or having reasonable cause to suspect that it was so imported shall be guilty of an offence.

(3) Any person who, being the holder of a product licence ...., procures another person to carry out a process in the manufacture or assembly of medicinal products of a description to which the licence … relates, and—

(a) does not communicate to that person the provisions of the licence … which are applicable to medicinal products of that description, or

(b) in a case where any of those provisions has been varied by a decision of the licensing authority, does not communicate the variation to that person within fourteen days after notice of the decision has been served on him,

shall be guilty of an offence.

(4) ...

(5) ...

(6) Any person who, in giving any information which he is required to give under section 44 of this Act, makes a statement which he knows to be false in a material particular shall be guilty of an offence.

(7) Any person who without reasonable excuse fails to comply with a requirement imposed on him by a notice under section 44(2) of this Act shall be guilty of an offence.

(8) Any person guilty of an offence under any of subsections (1) to (6) of this section shall be liable—

(a) on summary conviction, to a fine not exceeding £400;

(b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.

(9) Any person guilty of an offence under subsection (7) of this section shall be liable on summary conviction to a fine not exceeding level 3 on the standard scale.

46. Special defences under s. 45.

(1) Where the holder of a product licence …. is charged with an offence under the last preceding section in respect of any substance or article which has been manufactured (or, in the case of a medicinal product, manufactured or assembled) to his order by another person and has been so manufactured or assembled as not to comply with the provisions of that licence … which are applicable to it, it shall be a defence for him to prove—

(a) that he had communicated those provisions to that other person, and

(b) that he did not know, and could not by the exercise of reasonable care have discovered, that those provisions had not been complied with.

(2) Where the holder of a manufacturer's licence is charged with an offence under the last preceding section in respect of any medicinal products which have been manufactured or assembled by him, in circumstances where he is not the holder of a product licence . …. . which is applicable to those products, but the products were manufactured or assembled to the order of another person, it shall be a defence for him to prove that he believed, and had reasonable grounds for believing,—

(a) that the other person in question was the holder of a product licence applicable to those products, …., and

(b) that the products were manufactured or assembled in accordance with that product licence ….

(3) …

(4) …

47. Standard provisions for licences ….

(1) The Ministers may by regulations prescribe standard provisions for the purposes of this Part of this Act, either generally or in relation to any class of medicinal products specified in the regulations.

(2) Any standard provisions so prescribed may be incorporated by the licensing authority in any licence under this Part of this Act … granted … on or after the date on which the regulations come into operation, and may be so incorporated with or without modifications and either generally or in relation to medicinal products of any particular class.

(3) The following provisions of this section shall have effect where—

(a) standard provisions are prescribed by regulations made under this section, or

(b) after any such provisions have been so prescribed, they are amended by, or superseded by new standard provisions prescribed by, subsequent regulations so made;

and in the following provisions of this section, in a case falling within paragraph (a) but not within paragraph (b) of this subsection, "the operative standard provisions" means the standard provisions prescribed by the regulations and "the relevant regulations" means those regulations, and, in any other case, "the operative standard provisions" means the standard provisions as amended by the subsequent regulations or the new standard provisions prescribed by those regulations, as the case may be, and "the relevant regulations" means the subsequent regulations.

(4) Subject to the following provisions of this section, as from the end of the period of three months from the date on which the relevant regulations come into operation, the operative standard provisions shall be deemed to be incorporated in any licence under this Part of this Act, …, which is in force at the end of that period or, in the case of a suspended licence …, would then be in force if it were not suspended, in so far as, in accordance with the relevant regulations, the operative standard provisions are applicable to medicinal products of any description to which that licence … relates.

(5) Notwithstanding anything in subsection (4) of this section, the operative standard provisions shall not by virtue of that subsection be deemed to be incorporated in any licence of right, …, including any such licence … which has been renewed, except in circumstances where, immediately before the first appointed day, the manufacture or importation of substances or articles to which the licence … relates was authorised by a licence issued under Part I of the Therapeutic Substances Act 1956 or under Part II of the Diseases of Animals Act 1950, or of the Diseases of Animals Act (Northern Ireland) 1958, and, where those circumstances exist, shall be deemed to be so incorporated only in relation to substances or articles to which the licence so issued was applicable.

(6) At any time after the relevant regulations are made and before the end of the period of three months from the date on which they come into operation, the holder of any licence … may apply to the licensing authority to direct—

(a) that the operative standard provisions shall not be deemed to be incorporated in that licence …, or

(b) that the operative standard provisions shall be deemed to be so incorporated subject to such exceptions or modifications as may be specified in the application;

and if, on any such application, the licensing authority direct that the operative standard provisions shall not be deemed to be so incorporated, or shall be deemed to be so incorporated subject to exceptions and modifications specified in the direction, with or without provision postponing the date as from which they are to be deemed to be so incorporated, that direction shall have effect notwithstanding anything in subsection (4) of this section.

(7) Where an application is made to the licensing authority under subsection (6) of this section, then, if the licensing authority propose to refuse to give a direction in accordance with the application, the licensing authority, before determining the application, shall afford to the applicant an opportunity of appearing before, and being heard by, a person appointed for the purpose by the licensing authority, or of making representations in writing to the licensing authority with respect to that proposal; and, if the licensing authority then determine to refuse to give a direction in accordance with the application, they shall serve on the applicant a notice stating the reasons for their decision.

(8) Without prejudice to any direction given under subsection (6) of this section, where such an application is made—

(a) the operative standard provisions shall not be deemed to be incorporated in the licence … to which the application relates before the licensing authority have made a decision on that application, and

(b) if an application under section 107 of this Act is made with respect to that decision, those provisions shall not be deemed to have been or to be so incorporated before the application under subsection (6) of this section has been finally disposed of;

and so much of subsection (7) of section 27 of this Act as relates to the time when an application is to be taken to be finally disposed of shall have effect for the purposes of this subsection as it has effect for the purposes of that section.

(9) The powers conferred on the licensing authority by the preceding provisions of this Part of this Act to vary the provisions of a licence … shall be exercisable with respect to any provisions which, in accordance with this section, are incorporated or deemed to be incorporated in a licence ….

48. Postponement of restrictions in relation to exports.

(1) Notwithstanding anything in sections 7 to 47 of this Act but subject to section 49 … of this Act, in relation to anything done before such day (subsequent to the first appointed day) as the Ministers may by order appoint for the purposes of this subsection (in this section referred to as "the special appointed day") those sections shall have effect as if in them—

(a) every reference to exportation (in whatever form the reference occurs) were omitted;

(b) any reference to the sale or supply of a medicinal product did not include sale or supply which involves, or is for the purposes of, exporting the product; and

(c) any reference to offering a medicinal product for sale did not include an offer for sale where the prospective sale would involve, or would be for the purposes of, exporting the product.

(2) The Ministers shall not make an order under the preceding subsection unless it appears to them to be necessary or expedient to do so for the purpose of giving effect to an agreement to which the United Kingdom or Her Majesty's Government in the United Kingdom is a party or will be a party on the day appointed by the order.

(3) The following provisions of this section shall have effect where an order is made under subsection (1) of this section; and for the purposes of those provisions the relevant transitional conditions shall be taken to be fulfilled by a person in relation to medicinal products of any description if, in the course of a business carried on by him,—

(a) substantial quantities of medicinal products of that description (that is to say, quantities exceeding those required for distribution as samples) were exported or procured to be exported during the period of twenty-four months ending immediately before the special appointed day, and

(b) during the whole of that period further substantial quantities of medicinal products of that description were available, or could within a reasonable time have been made available, to be so exported or procured to be exported if required.

(4) Unless the order expressly excludes the operation of this subsection,—

(a) subject to any order made by virtue of paragraph (b) of this subsection, section 7(2) of this Act shall not have effect in relation to a person in respect of his exporting on or after the special appointed day, or procuring the exportation on or after that day of, medicinal products of any description in relation to which he fulfils the relevant transitional conditions;

(b) section 17 of this Act shall have effect in relation to paragraph (a) of this subsection as it has effect in relation to the subsections of section 16 of this Act mentioned in that section.

(5) Where a product licence which is in force on the special appointed day authorises the holder of the licence to sell medicinal products of any description, or to procure the sale, or procure the manufacture or assembly for sale, of medicinal products of any description, that licence shall have effect on and after that day as if—

(a) it also authorised him to export medicinal products of that description, or (as the case may be) to procure the exportation, or procure the manufacture or assembly for exportation, of medicinal products of that description, and

(b) it authorised him to do so subject to the like provisions as (apart from subsections (3) to (7) of section 47 of this Act) are specified in the licence in relation to selling or (as the case may be) procuring the sale, or procuring the manufacture or assembly for sale, of such products:

Provided that, if the operation of subsection (4) of this section is not excluded by the order, a product licence shall not have effect as mentioned in this subsection in relation to medicinal products of any description so long as paragraph (a) of that subsection has effect in relation to the holder of the licence in respect of his exporting, or procuring the exportation of, medicinal products of that description.

(6) Where on an application for a product licence made before such date as may be appointed by the order for the purposes of this subsection, which states that it is an application made by virtue of this subsection, it is proved to the reasonable satisfaction of the licensing authority that the applicant fulfilled or will fulfil the relevant transitional conditions in relation to one or more descriptions of medicinal products, then (subject to the next following subsection) he shall be entitled to the grant of a product licence granted so as—

(a) to be limited to exportation, or procuring exportation, of medicinal products, and

(b) not to extend to medicinal products of any description other than those in respect of which it is so proved that the applicant fulfilled or will fulfil those conditions, and

(c) not to extend to medicinal products of any description in respect of which, at the time when the licence is granted, a product licence is already held by the applicant.

(7) If a person would, on making an application under subsection (6) of this section, be entitled to the grant of a product licence under that subsection in respect of medicinal products of a particular description, and he would at the same time, on making an application as mentioned in section 25(1) of this Act, be entitled to the grant of a licence of right in respect of medicinal products of the same description, he may apply to the licensing authority for a single product licence for both purposes, and he shall be entitled to the grant of a product licence having the same effect as the two licences, if granted separately, would together have had.

(8) Subsection (6) of section 26 of this Act shall have effect for the purposes of subsections (6) and (7) of this section as it has effect for the purposes of that section.

(9) An order made under subsection (1) of this section may contain such provisions relating to proceedings on an application made under subsection (6) or subsection (7) of this section (whether by way of applying with modifications any of the provisions of section 27 of this Act or otherwise) as the Ministers may consider appropriate.

(10) No order shall be made under this section unless a draft of the order has been laid before Parliament and approved by a resolution of each House of Parliament.

49. Special provisions in respect of exporting certain products.

(1) Nothing in subsection (1) of section 48 of this Act shall affect the operation of any of the provisions of sections 7 to 47 of this Act in relation to any medicinal product falling within a class specified in an order made under this section by the…. Ministers.

(2) No class of medicinal products shall be specified in an order made by … Ministers under this section unless it appears to them to be requisite to do so for securing that any exemption conferred by section 48(1) of this Act does not apply to medicinal products consisting wholly or partly of substances the purity or potency of which cannot, in their opinion, be adequately tested by chemical means.

(3) Subsections (3) to (7) of section 48 of this Act shall not have effect in relation to medicinal products of any description falling within a class specified in an order under this section which is in force immediately before the day appointed for the purposes of subsection (1) of that section.

(4) Subject to the next following subsection, section 7(2) of this Act shall not have effect in relation to a person in respect of his exporting, or procuring the exportation of, medicinal products of any description falling within a class specified in an order under this section which is in force immediately before the first appointed day if, in the course of a business carried on by that person,—

(a) substantial quantities of medicinal products of that description (that is to say, quantities exceeding those required for distribution as samples) were exported or procured to be exported during the period of twenty-four months ending with the first appointed day, and

(b) during the whole of that period further substantial quantities of medicinal products of that description were available, or could within a reasonable time have been made available, to be so exported or procured to be exported if required.

(5) Sections 17 and 25 of this Act shall have effect in relation to subsection (4) of this section as they have effect in relation to subsections (2) to (5) of section 16 of this Act.

(6) Where a person is entitled to the grant of a licence of right by reason that subsection (4) of this section has effect in relation to him, he shall be entitled to the grant of a product licence; but, subject to the next following subsection, the licence shall be granted so as not to extend to medicinal products of any description other than those in respect of which the conditions specified in that subsection are proved to the reasonable satisfaction of the licensing authority to have been fulfilled, and shall be limited to exporting, or procuring the exportation of, medicinal products.

(7) Subsection (5) of section 26 of this Act (with the omission of paragraph (b) of that subsection) and subsection (6) of that section shall have effect in relation to the grant of a licence of right in accordance with subsection (6) of this section as those subsections have effect in relation to the grant of such a licence in accordance with subsection (1) of that section.

(8) In relation to any application for a licence of right which is made by virtue of section 25 of this Act as applied by subsection (5) of this section, the provisions of section 27 of this Act shall have effect subject to such modifications as may be specified by order made by the Ministers for the purposes of this subsection.

49A. Special provisions in respect of exporting certain products to member States,

Nothing in subsection (1) of section 48 of this Act shall affect the operation of section 8(3A) of this Act in relation to the exportation of a product, or the sale or supply of a product which involves, or is for the purposes of, the exportation of the product if—

(a) it is a product to which the 2001 Directive applies; and

(b) the exportation is, or is to be, to a member State.

50. Certificates for exporters of medicinal products.

On the application of any person who proposes to export medicinal products of any description, the licensing authority may issue to him a certificate containing any such statement relating to medicinal products of that description as the licensing authority may consider appropriate having regard—

(a) to any requirements (whether having the force of law or not) which have effect in the country to which the products are to be exported, and

(b) to the provisions of this Act and to any licence granted or other thing done by virtue of this Act, and

(c) to the provisions of the Clinical Trials Regulations and to any authorisation granted or other thing done by virtue of those regulations.

Part III

Further provisions relating to dealings with medicinal products

Provisions as to sale or supply of medicinal products

51. General sale lists.

(1) The … Ministers may by order specify descriptions or classes of medicinal products, as being products which in their opinion can with reasonable safety be sold or supplied otherwise than by, or under the supervision of, a pharmacist.

(2) In this Act any reference to a medicinal product on a general sale list is a reference to a medicinal product of a description, or falling within a class, specified in an order under this section which is for the time being in force.

(3) An order under this section may designate any description or class of medicinal products specified in the order as being medicinal products which, in the opinion of the … Ministers, can with reasonable safety be sold by means of automatic machines; and any reference in this Act to a medicinal product in the automatic machines section of a general sale list is a reference to a medicinal product of a description, or falling within a class, so designated by any such order which is for the time being in force.

52. Sale or supply of medicinal products not on general sale list.

(1) Subject to any exemption conferred by or under this Part of this Act, on and after such day as the Ministers may by order appoint for the purposes of this section (in this Part of this Act referred to as "the appointed day") no person shall, in the course of a business carried on by him, sell by retail, offer or expose for sale by retail, or supply in circumstances corresponding to retail sale, any medicinal product which is not a medicinal product on a general sale list, unless—

(a) that person is, in respect of that business, a person lawfully conducting a retail pharmacy business;

(b) the product is sold, offered or exposed for sale, or supplied, on premises which are a registered pharmacy; and

(c) that person, or, if the transaction is carried out on his behalf by another person, then that other person, is, or acts under the supervision of, a pharmacist.

(2) The … Ministers may make regulations prescribing conditions which must be complied with if a transaction mentioned in subsection (1)(c) is to be considered for the purposes of this section as done under the supervision of a pharmacist.

(3) Conditions prescribed under subsection (2) may relate to supervision in the case where the pharmacist is not on the premises, and in that case the transaction is not to be so considered if no such conditions are prescribed.

(4) In any case, compliance with any applicable conditions is sufficient for the transaction to be so considered.

53. Sale or supply of medicinal products on general sale list.

(1) Subject to any exemption conferred by or under this Part of this Act, on and after the appointed day no person shall, in the course of a business carried on by him, sell by retail, or offer or expose for sale by retail, or supply in circumstances corresponding to retail sale, any medicinal product on a general sale list elsewhere than at a registered pharmacy, unless the conditions specified in the following provisions of this section are fulfilled.

(2) The place at which the medicinal product is sold, offered, exposed or supplied as mentioned in the preceding subsection must be premises of which the person carrying on the business in question is the occupier and which he is able to close so as to exclude the public, unless …—

(a) the product is sold, offered, exposed for sale or supplied by means of an automatic machine and the product is a medicinal product in the automatic machines section of a general sale list, …

(b) ….

(3) The medicinal product must have been made up for sale in a container elsewhere than at the place at which it is sold, offered, exposed for sale or supplied as mentioned in subsection (1) of this section and the container must not have been opened since the product was made up for sale in it.

(4) The business, so far as concerns the sale or supply of medicinal products, must be carried on in accordance with such conditions (if any) as may be prescribed for the purposes of this section.

54. Sale of medicinal products from automatic machines.

(1) On and after the appointed day no person shall sell, or offer or expose for sale, any medicinal product by means of an automatic machine unless it is a medicinal product in the automatic machines section of a general sale list.

(2) The … Ministers may by order provide that no person shall by means of an automatic machine sell, or offer or expose for sale, any medicinal product to which the order applies unless the container in which it is sold, or offered or exposed for sale, complies with such restrictions as to the quantity of the medicinal product, or the number of medicinal products, which it contains as may be specified in the order.

(3) An order under subsection (2) of this section may be made either in respect of medicinal products generally or in respect of medicinal products of a particular description or falling within a particular class specified in the order.

Exemptions from sections 52 and 53

55. Exemptions for doctors and dentists, etc….

(1) The restrictions imposed by sections 52 and 53 of this Act do not apply to the sale, offer for sale, or supply of a medicinal product—

(a) by a doctor or dentist to a patient of his or to a person under whose care such a patient is, or

(b) in the course of the business of a hospital or health centre, where the product is sold, offered for sale or supplied for the purpose of being administered (whether in the hospital or health centre or elsewhere) in accordance with the directions of a doctor or dentist.

(2) Those restrictions also do not apply—

(a) to the sale or supply of a medicinal product of a description, or falling within a class, specified in an order made by the … Ministers for the purposes of this paragraph, where the product is sold or supplied by a registered nurse in the course of her professional practice, or

(b) to the sale or supply of a medicinal product of a description, or falling within a class, specified in an order made by the … Ministers for the purposes of this paragraph, where the product either is sold or supplied by a certified midwife (or, in relation to England and Wales, by a certified midwife or exempted midwife) in the course of her professional practice or is delivered or administered by such a midwife on being supplied in pursuance of arrangements made by the Secretary of State or the Ministry of Health and Social Services for Northern Ireland.

(3) ….

(4) Expressions to which a meaning is assigned by subsection (2) of section 11 of this Act have the same meanings in this section as in that section.

56. Exemptions in respect of herbal remedies.

(1) Subject to the following provisions of this section, the restrictions imposed by sections 52 and 53 of this Act do not apply to anything done at premises of which the person carrying on the business in question is the occupier and which he is able to close so as to exclude the public, and which consists of the sale, or offer or exposure for sale, or the supply in circumstances corresponding to retail sale, of a herbal remedy where the processes to which the plant or plants are subjected consist of drying, crushing or comminuting, with or without any subsequent process of tabletting, pill-making, compressing or diluting with water, but not any other process.

(2) Without prejudice to the preceding subsection, but subject to subsection (3) of this section, those restrictions do not apply to the sale or supply of a herbal remedy where the person selling or supplying the remedy sells or supplies it for administration to a particular person after being requested by or on behalf of that person and in that person's presence to use his own judgment as to the treatment required.

(3) The … Ministers may by order provide that subsections (1) and (2) of this section shall not have effect in relation to herbal remedies of a description, of falling within a class, specified in the order.

57. Power to extend or modify exemptions.

(1) The … Ministers may by order provide that section 52 or section 53 of this Act, or both of those sections, shall have effect subject to such exemptions (other than those for the time being having effect by virtue of sections 55 and 56 of this Act) as may be specified in the order.

(2) Any exemption conferred by an order under the preceding subsection may be conferred subject to such conditions or limitations as may be specified in the order.

(2A) ….

(2B….

(2C) ….

(2D) ….

(3) The … Ministers may by order provide that subsection (1)(b) or subsection (2) of section 55 of this Act shall cease to have effect, or shall have effect subject to such exceptions or modifications as may be specified in the order.

(4) No order shall be made under subsection (3) of this section unless a draft of the order has been laid before Parliament and approved by a resolution of each House of Parliament.

Additional provisions

58. Medicinal products on prescription only.

(1) The … Ministers may by order specify descriptions or classes of medicinal products for the purposes of this section; and, in relation to any description or class so specified, the order shall state which of the following, that is to say—

(a) doctors,

(b) dentists,

(c) veterinary surgeons and veterinary practitioners,

(d) registered nurses or midwives who are of such a description and comply with such conditions as may be specified in the order, and

(e) other persons who are of such a description and comply with such conditions as may be specified in the order.

(1A) The descriptions of persons which may be specified in an order by virtue of subsection (1)(e) are the following, or any sub-category of such a description—

(a) persons who are registered in the register maintained under article 5 of the Health Professions Order 2001;

(b) persons who are pharmacists;

(c) persons whose names are entered in a roll or record established by the General Dental Council by virtue of section 45 of the Dentists Act 1984 (c. 24) (dental auxiliaries);

(d) persons who are registered in either of the registers of ophthalmic opticians kept under section 7(a) of the Opticians Act 1989 (c. 44);

(e) persons who are registered osteopaths within the meaning of the Osteopaths Act 1993 (c. 21);

(f) persons who are registered chiropractors within the meaning of the Chiropractors Act 1994 (c. 17);

(g) persons who are registered in any register established, continued or maintained under an Order in Council under section 60(1) of the Health Act 1999 (c. 8);

(h) any other description of persons which appears to the … Ministers to be a description of persons whose profession is regulated by or under a provision of, or made under, an Act of the Scottish Parliament or Northern Ireland legislation and which the …. Ministers consider it appropriate to specify are to be appropriate practitioners for the purposes of this section.

(1B) ….

(2) Subject to the following provisions of this section—

(a) no person shall sell by retail, or supply in circumstances corresponding to retail sale, a medicinal product of a description, or falling within a class, specified in an order under this section except in accordance with a prescription given by an appropriate practitioner; and

(b) no person shall administer (otherwise than to himself) any such medicinal product unless he is an appropriate practitioner or a person acting in accordance with the directions of an appropriate practitioner.

(3) Subsection (2)(a) of this section shall not apply—

(a) to the sale or supply of a medicinal product to a patient of his by a doctor or dentist who is an appropriate practitioner…

(b) ….

(4) Without prejudice to the last preceding subsection, any order made by the … Ministers for the purposes of this section may provide—

(a) that paragraph (a) or paragraph (b) of subsection (2) of this section, or both those paragraphs, shall have effect subject to such exemptions as may be specified in the order or, where the appropriate practitioner is a registered nurse or midwife, or is an appropriate practitioner by virtue of provision made under subsection (1)(e) of this section, such modifications as may be so specified;

(b) that, for the purpose of paragraph (a) of that subsection, a medicinal product shall not be taken to be sold or supplied in accordance with a prescription given by an appropriate practitioner unless such conditions as are prescribed by the order are fulfilled.

(4A) An order under this section may provide, in relation to a person who is an appropriate practitioner by virtue of subsection (1)(d) or (e), that such a person may—

(a) give a prescription for a medicinal product falling within a description or class specified in the order;

(b) administer any such medicinal product; or

(c) give directions for the administration of any such medicinal product,

only where he complies with such conditions as may be specified in the order in respect of the cases or circumstances in which he may do so.

(4B) An order under this section may provide, in relation to a condition specified by virtue of subsection (4A), for the condition to have effect subject to such exemptions as may be specified in the order.

(4C) Where a condition is specified by virtue of subsection (4A), any prescription or direction given by a person in contravention of the condition is not (subject to such exemptions or modifications as may be specified in the order by virtue of subsection (4)(a) of this section) given by an appropriate practitioner for the purposes of subsection (2)(a) or (b) of this section.

(5) Any exemption conferred or modification made by an order in accordance with subsection (4)(a) of this section may be conferred or made subject to such conditions or limitations as may be specified in the order.

(6) Before making an order under this section the … Ministers shall consult the appropriate committee….

58A. Requirement to specify certain products … as prescription-only products.

(1) The … Ministers shall, subject to subsection (4) of this section, so exercise their powers under section 58(1) of this Act as to secure that every product—

(a) in respect of which a product licence is granted;

(b) to which the 2001 Directive applies; and

(c) to which subsection (2) of this section applies;

falls within one of the descriptions or classes specified for the purposes of section 58.

(2) This subsection applies to any product which—

(a) is likely to present a direct or indirect danger to human health, even when used correctly, if used without the supervision of a doctor or dentist; or

(b) is frequently and to a very wide extent used incorrectly, and as a result is likely to present a direct or indirect danger to human health; or

(c) contains substances or preparations of substances of which the activity requires, or the side-effects require, further investigation; or

(d) is normally prescribed by a doctor or dentist for parenteral administration.

(3) In considering whether subsection (2) of this section applies to a product the … Ministers shall take into account whether the product—

(a) contains a substance which is listed in any of Schedules I, II or IV to the Narcotic Drugs Convention (where the product is not a preparation listed in Schedule III to that Convention); or

(b) contains a substance which is listed in any of Schedules I to IV of the Psychotropic Substances Convention (where the pro duct is not a preparation which may be exempted from measures of control in accordance with paragraphs 2 and 3 of article 3 of that Convention); or

(c) is likely, if incorrectly used—

(i) to present a substantial risk of medicinal abuse, or

(ii) to lead to addiction, or

(iii) to be used for illegal purposes; or

(d) contains a substance which, by reason of its novelty or properties, might fall within paragraph (c) above, but as to which there is insufficient information available to determine whether it does so fall; or

(e) by reason of its pharmaceutical characteristics or novelty, or in the interests of public health, is reserved for treatments which can only be followed in a hospital; or

(f) is used in the treatment of conditions which must be diagnosed in a hospital or in an institution with special diagnostic facilities (although administration and subsequent supervision may be carried out elsewhere); or

(g) is intended for outpatients but may produce very serious side effects which would require a prescription drawn up as required by a specialist and special supervision throughout the treatment.

(4) Subsection (1) of this section shall not apply in relation to any product if the … Ministers so determine having regard to—

(a) the maximum single dose;

(b) the maximum daily dose;

(c) the strength of the product;

(d) its pharmaceutical form;

(e) its packaging; or

(f) such other circumstances relating to its use as may be specified in the determination.

(5) In this section …—

"the Narcotic Drugs Convention" means the Single Convention on Narcotic Drugs signed by the United Kingdom on 30th March 1961 as amended by the Protocol Amending the Single Convention on Narcotic Drugs signed by the United Kingdom on 25th March 1972; and

"the Psychotropic Substances Convention" means the Convention on Psychotropic Substances signed by the United Kingdom on 21st February 1971.

58B. ….

59. Special provisions in relation to new medicinal products.

(1) The following provisions of this section shall have effect where an order under section 58 of this Act is made so as to apply to all medicinal products which fall within a class specified in the order and are of a description in respect of which the following conditions are fulfilled, that is to say, that—

(a) medicinal products of that description were not effectively on the market in the United Kingdom immediately before the first appointed day;

(b) a product licence granted under Part II of this Act (whether before, on or after the date on which the order comes into operation) applies to medicinal products of that description (whether it also applies to medicinal products of any other description or not); and

(c) before the grant of that licence, no product licence had been granted which was applicable to medicinal products of that description.

(2) Where such an order is made in accordance with the preceding subsection—

(a) the restrictions imposed by section 58(2) of this Act shall not apply by virtue of the order to medicinal products of any description except during a period beginning with the date which, in relation to medicinal products of that description, is the relevant date and of such duration from that date as may be specified in the order;

(b) in section 58(4)(a) of this Act the reference to exemptions specified in the order shall, in relation to that order, be construed as including a reference to any exemption specified in a direction given by the … Ministers and relating to medicinal products of a particular description specified in that direction.

(3) In subsection (2)(a) of this section "the relevant date", in relation to medicinal products of any description to which an order made in accordance with subsection (1) of this section applies, means the date on which the order comes into operation, or the date on which the product licence applicable to medicinal products of that description (as mentioned in subsection (1)(b) of this section) comes into operation, whichever is the later.

60. Restricted sale, supply and administration of certain medicinal products.

(1) Subject to the following provisions of this section, regulations made by the … Ministers may provide that no person shall sell by retail, or supply in circumstances corresponding to retail sale, a medicinal product of a description specified in the regulations, or falling within a class so specified, unless—

(a) he is a practitioner holding a certificate issued for the purposes of this section by the … Ministers in respect of medicinal products of that description or falling within that class, or a person acting in accordance with the directions of such a practitioner, and the product is so sold or supplied for the purpose of being administered in accordance with the directions of that practitioner, or

(b) he is a person lawfully conducting a retail pharmacy business and the product is so sold or supplied in accordance with a prescription given by such a practitioner.

(2) Any regulations made under this section may provide that no person shall administer (otherwise than to himself) a medicinal product of a description specified in the regulations, or falling within a class so specified, unless he is such a practitioner as is mentioned in subsection (1)(a) of this section or a person acting in accordance with the directions of such a practitioner.

(3) The powers conferred by the preceding subsections shall not be exercisable in respect of medicinal products of a particular description, or falling within a particular class, except where it appears to the … Ministers that the sale by retail, or supply in circumstances corresponding to retail sale, or the administration, of such products requires specialised knowledge on the part of the practitioner by whom or under whose directions they are sold, supplied or administered.

(4) Any regulations made under this section in respect of a particular description or class of medicinal products may specify the qualifications and experience which an applicant for a certificate in respect of that description or class of medicinal products must have, and may provide for the appointment of a committee to advise the … Ministers, in such cases as may be prescribed by or determined in accordance with the regulations, with respect to the grant, renewal, suspension and revocation of such certificates.

(5) Any such regulations shall include provision as to the grant, duration, renewal, suspension and revocation of certificates for the purposes of this section, including provision for affording—

(a) to an applicant for the grant or renewal of such a certificate, where the … Ministers propose to refuse to grant or renew it, and

(b) to the holder of such a certificate, where the … Ministers propose to suspend or revoke it,

an opportunity of appearing before, and being heard by, a person appointed for the purpose by the … Ministers or of making representations in writing to the Ministers with respect to that proposal.

(6) Regulations made under this section may provide that, for the purposes of paragraph (b) of subsection (1) of this section, a medicinal product shall not be taken to be sold or supplied in accordance with a prescription as mentioned in that paragraph unless such conditions as are prescribed by the regulations are fulfilled.

(7) Before making any regulations under this section the … Ministers shall consult the appropriate committee.

61. Special restrictions on persons to be supplied with medicinal products.

The … Ministers may by regulations provide, either in respect of medicinal products generally or in respect of medicinal products of a description or falling within a class specified in the regulations, that, subject to such exceptions as may be so specified, no person—

(a) being the holder of a product licence, or

(b) in the course of business carried on by him and consisting (wholly or partly) of manufacturing medicinal products or of selling medicinal products by way of wholesale dealing,

shall sell or supply any medicinal product to which the regulations apply to any person who does not fall within a class specified in the regulations.

62. Prohibition of sale or supply, or importation, of medicinal products of specified description….

(1) Subject to the following provisions of this section, the … Ministers, where it appears to them to be necessary to do so in the interests of safety, may by order—

(a) prohibit the sale or supply, or the importation, of medicinal products of any description, or falling within any class, specified in the order, or (in such manner as may appear to them to be sufficient to identify the products in question) designate particular medicinal products and prohibit the sale or supply, or the importation, of those particular products;

(b) ...

(2) A prohibition imposed by order under this section may be a total prohibition or may be imposed subject to such exceptions as may be specified in the order.

(3) Before making an order under this section the … Ministers, unless in their opinion it is essential to make the order with immediate effect to avoid serious danger to health, …, shall consult the appropriate committee….

(4) Where an order is made under this section without prior consultation with the appropriate committee … in accordance with subsection (3) of this section, the prohibition imposed by the order shall not have effect after the end of such period, not exceeding three months from the date on which it comes into operation, as may be specified in the order, but without prejudice to the making of any further order in accordance with the provisions of this section (including this subsection).

(5) If any organisation consulted in pursuance of section 129(6) of this Act with respect to a proposal to make an order under this section have given notice to the … Ministers of their desire to be heard under this subsection, or have made representations in writing to the Ministers with respect to that proposal, then before making the order—

(a) if the organisation have given notice of their desire to be heard, the … Ministers shall arrange for them to have an opportunity of appearing before, and being heard by, the appropriate committee, or

(b) if they have made representations in writing, the … Ministers shall refer those representations to the appropriate committee,

and, where the organisation have availed themselves of the opportunity of being heard, or after considering the representations, as the case may be, the appropriate committee shall report their findings and conclusions to the … Ministers and the Ministers shall take that report into account in determining whether to make the order.

(6) Subsection (5) of this section shall not have effect where in the opinion of the … Ministers it is essential to make the order with immediate effect as mentioned in subsection (3) of this section.

(7) If an order is made under this section and either -

(a) the appropriate committee have not considered the proposal to make the order, or

(b) the order is made contrary to the advice of the appropriate committee,

the order shall include a statement of the fact that it has been so made.

63. **Adulteration of medicinal products.**

No person shall—

(a) add any substance to, or abstract any substance from, a medicinal product so as to affect injuriously the composition of the product, with intent that the product shall be sold or supplied in that state, or

(b) sell or supply, or offer or expose for sale or supply, or have in his possession for the purpose of sale or supply, any medicinal product whose composition has been injuriously affected by the addition or abstraction of any substance.

64. **Protection of purchasers of medicinal products.**

(1) No person shall, to the prejudice of the purchaser, sell any medicinal product which is not of the nature or quality demanded by the purchaser.

(2) For the purposes of this section the sale of a medicinal product shall not be taken to be otherwise than to the prejudice of the purchaser by reason only that the purchaser buys the product for the purpose of analysis or examination.

(3) Subsection (1) of this section shall not be taken to be contravened by reason only that a medicinal product contains some extraneous matter, if it is proved that the presence of that matter was an inevitable consequence of the process of manufacture of the product.

(4) Subsection (1) of this section shall not be taken to be contravened by reason only that a substance has been added to, or abstracted from, the medicinal product, if it is proved that—

(a) the addition or abstraction was not carried out fraudulently, and did not injuriously affect the composition of the product, and

(b) the product was sold having attached to it, or to a container or package in which it was sold, a conspicuous notice of adequate size and legibly printed, specifying the substance added or abstracted.

(5) Where a medicinal product is sold or supplied in pursuance of a prescription given by a practitioner, the preceding provisions of this section shall have effect as if—

(a) in those provisions any reference to sale included a reference to supply and (except as provided by the following paragraph) any reference to the purchaser included a reference to the person (if any) for whom the product was prescribed by the practitioner, and

(b) in subsection (1) of this section, for the words “demanded by the purchaser”, there were substituted the words “specified in the prescription”.

65. Compliance with standards specified in monographs in certain publications.

(1) No person shall, in the course of a business carried on by him,—

(a) sell a medicinal product which has been demanded by the purchaser by, or by express reference to, a particular name, or

(b) sell or supply a medicinal product in pursuance of a prescription given by a practitioner in which the product required is described by, or by express reference, to a particular name,

if that name is a name at the head of the relevant monograph and the product does not comply with the standard specified in that monograph.

(2) No person shall, in the course of a business carried on by him, sell or supply a medicinal product which, in the course of that business, has been offered or exposed for sale and has been so offered or exposed for sale by, or by express reference to, a particular name, if that name is a name at the head of the relevant monograph and the product does not comply with the standard specified in that monograph.

(3) Where a medicinal product is sold or supplied in the circumstances specified in subsection (1) or subsection (2) of this section, and the name in question is the name, not of the product itself, but of an active ingredient of the product, then for the purposes of the subsection in question the product shall be taken not to comply with the standard specified in the relevant monograph if, in so far as it consists of that ingredient, it does not comply with the standard so specified.

(4) Subject to subsection (7) of this section, in this section "publication" means one of the following, that is to say, the British Pharmacopoeia, the British Pharmaceutical Codex… and any compendium published under Part VII of this Act; "the relevant monograph", in relation to the sale or supply of a medicinal product which has been demanded, described in a prescription, or offered or exposed for sale, by or by express reference to a particular name,—

(a) if, together with that name, there was specified a particular edition of a particular publication, means the monograph (if any) headed by that name in that edition of that publication, or, if there is no such monograph in that edition, means the appropriate current monograph (if any) headed by that name;

(b) if, together with that name, there was specified a particular publication, but not a particular edition of that publication, means the monograph (if any) headed by that name in the current edition of that publication, or, if there is no such monograph in that edition, means the appropriate current monograph (if any) headed by that name, or, in default of such a monograph, means the monograph headed by that name in the latest edition of the specified publication which contained a monograph so headed;

(c) if no publication was specified together with that name, means the appropriate current monograph (if any);

and "current" means current at the time when the medicinal product in question is demanded, described in a prescription, or offered or exposed for sale, as mentioned in subsection (1) or subsection (2) of this section.

(5) In this section "the appropriate current monograph", in relation to a particular name, means—

(a) the monograph (if any) headed by that name in the current edition of the British Pharmacopoeia, or

(b) if there is no such monograph, then the monograph (if any) headed by that name in the current edition of a compendium published under Part VII of this Act, or

(c) if there is no such monograph, then the monograph (if any) headed by that name in the current edition of the British Pharmaceutical Codex ….

(6) Subject to subsection (8) of this section, for the purposes of this section an edition of a publication—

(a) if it is the current edition of that publication, shall be taken as it is for the time being in force (that is to say, together with any amendments, additions and deletions made to it up to the time referred to in subsection (4) of this section), or

(b) if it is an edition previous to the current edition of that publication, shall be taken as it was immediately before the time when it was superseded by a subsequent edition of that publication (that is to say, together with any amendments, additions and deletions made to it up to that time),

and any monograph in an edition of a publication shall be construed in accordance with any general monograph or notice or any appendix, note or other explanatory material which is contained in that edition and is applicable to that monograph, and any reference in this section to compliance with the standard specified in a monograph shall be construed accordingly.

(7) In relation to any time on or after the date on which, by notice published in the Gazette by or on behalf of the … Ministers, it is declared that the European Pharmacopoeia prepared in pursuance of the Convention in that behalf done at Strasbourg on 22nd July 1964 is to have effect for the purposes of this section, subsections (1) and (2) of this section shall have effect as if, after the words "that name is", in each place where those words occur, there were inserted the words "or is an approved synonym for," subsection (4) of this section shall have effect as if, before the words "the British Pharmacopoeia", there were inserted the words "the European Pharmacopoeia", and after the words "headed by that name", in each place where those words occur, there were inserted the words "or by a name for which it is an approved synonym", and subsection (5) of this section shall have effect as if for paragraph (a) of that subsection there were substituted the following paragraphs:—

(a) the monograph (if any) headed by that name, or by a name for which it is an approved synonym, in the current edition of the European Pharmacopoeia, or

(aa) if there is no such monograph, then the monograph (if any) headed by that name in the current edition of the British Pharmacopoeia, or

(8) For the purposes of this section, an edition of the European Pharmacopoeia—

(a) if it is the current edition of that Pharmacopoeia at the time in question, shall be taken as it is for the time being in force in the United Kingdom (that is to say, together with any amendments, additions and deletions made to it which, by notice published as mentioned in subsection (7) of this section before the time referred to in subsection (4) of this section, have been declared to have effect for the purposes of this section), and

(b) if it is an edition previous to the current edition of that Pharmacopoeia, shall be taken as it was immediately before the time when it was superseded by a subsequent edition of that Pharmacopoeia in force in the United Kingdom (that is to say, together with any amendments, additions and deletions made to it which, by notice so published before that time, had been declared so to have effect),

and a name shall be taken to be an approved synonym for a name at the head of a monograph in the European Pharmacopoeia if, by a notice so published and not withdrawn by any subsequent notice so published, it has been declared to be approved by the Commission as a synonym for that name.

66. Further powers to regulate dealings with medicinal products.

(1) The … Ministers may by regulations prescribe such requirements as they may consider necessary or expedient with respect to any of the following matters, that is to say—

(a) the manner in which, or persons under whose supervision, medicinal products may be prepared or may be dispensed;

(b) the amount of space to be provided in any premises for persons preparing or dispensing medicinal products, the separation of any such space from the remainder of the premises, and the facilities to be provided in any premises for such persons;

(c) the amount of space to be provided in any premises for the sale or supply of medicinal products;

(d) the accommodation (including the amount of space) to be provided in any premises for members of the public to whom medicinal products are sold or supplied or for whom medicinal products are being prepared or assembled;

(e) the amount of space to be provided in any premises for the storage of medicinal products;

(f) the safekeeping of medicinal products;

(g) the disposal of medicinal products which have become unusable or otherwise unwanted;

(h) precautions to be observed before medicinal products are sold or supplied;

(i) the keeping of records relating to the sale or supply of medicinal products;

(j) the supply of medicinal products distributed as samples;

(k) sanitation, cleanliness, temperature, humidity or other factors relating to the risks of deterioration or contamination in connection with the manufacture, storage, transportation, sale or supply of medicinal products;

(l) the construction, location and use of automatic machines for the sale of medicinal products.

(2) Without prejudice to the generality of the preceding subsection, regulations made under subsection (1) of this section may prescribe requirements in respect of—

(a) the construction, lay-out, drainage, equipment, maintenance, ventilation, lighting and water supply of premises at or from which medicinal products are manufactured, stored, transported, sold or supplied;

(b) the disposal of refuse at or from any such premises; and

(c) any apparatus, equipment, furnishings or utensils used at any such premises.

Offences, and provision for disqualification

67. Offences under Part III.

(1) The following provisions of this section shall have effect subject to sections 121 and 122 of this Act.

(1A) Any person who gives a prescription or directions or administers a medicinal product in contravention of a condition imposed by an order under section 58 of this Act by virtue of subsection (4A) of that section shall be guilty of an offence.

(1B) Any person who—

(a) is an appropriate practitioner by virtue of provision made under section 58(1) of this Act; and

(b) gives a prescription or directions in respect of a medicinal product of a description or class in relation to which he is not an appropriate practitioner,

shall be guilty of an offence.

(2) Any person who contravenes any of the following provisions of this Part of this Act, that is to say, sections 52, 58, 63, 64 and 65, or who contravenes any regulations made under section 60 or section 61 or any order made under section 62 of this Act, shall be guilty of an offence.

(3) Where a medicinal product is sold, supplied or imported in contravention of an order made under section 62 of this Act, any person who, otherwise than for the purpose of performing or exercising a duty or power imposed or conferred by or under this Act or any other enactment, is in possession of the medicinal product, knowing or having reasonable cause to suspect that it was sold, supplied or imported in contravention of the order, shall be guilty of an offence.

(4) Any person guilty of an offence under subsection (1A), (1B), subsection (2) or subsection (3) of this section shall be liable—

(a) on summary conviction, to a fine not exceeding £400;

(b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.

(5) Any person who contravenes section 53 or section 54(1) or an order made under section 54(2) of this Act shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 3 on the standard scale.

(6) Any regulations made under section 66 of this Act may provide that any person who contravenes the regulations shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale or such lesser sum as may be specified in the regulations.

68. Disqualification on conviction of certain offences.

(1) Where in proceedings brought by an enforcement authority a person is convicted of an offence under section 67(6) of this Act in respect of any premises used for carrying on a retail pharmacy business, then on the application of that authority the court by or before which he was convicted may (subject to the following provisions of this section) make an order disqualifying him from using those premises for the purposes of such a business for such period, not exceeding two years, as may be specified in the order.

(2) The court shall not make an order under this section disqualifying a person in respect of any premises unless the court thinks it expedient to do so having regard—

(a) to the gravity of the offence of which he has been convicted as mentioned in the preceding subsection, or

(b) to the unsatisfactory nature of the premises, or

(c) to any offences under section 67(6) of this Act of which he has previously been convicted.

(3) No order under this section shall be made against a person on the application of an enforcement authority unless the authority have, not less than fourteen days before the date of the hearing, given him notice in writing of their intention to apply for such an order to be made against him.

(4) If, while an order under this section disqualifying a person in respect of any premises is in force, the premises are used for the purposes of a retail pharmacy business carried on by him, he shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale.

(5) Subject to the next following subsection, at any time after the end of the period of six months from the date on which an order under this section comes into force, the person to whom the order relates may apply to the court by which the order was made to revoke the order or to vary it by reducing the period of disqualification.

(6) On any application made under subsection (5) of this section the court may revoke or vary the order as mentioned in that subsection if it thinks it proper to do so having regard to all the circumstances of the case, including in particular the conduct of the applicant and any improvement in the state of the premises to which the order relates; but, if on any such application the court refuses to revoke or vary the order, no further application made by the applicant under that subsection shall be entertained if it is made within three months from the date of the refusal.

(7) The court to which an application under subsection (5) of this section is made shall have power to order the applicant to pay the whole or any part of the costs of the application.

(8) In the application of this section to Scotland, for references to an enforcement authority and to costs there shall be substituted respectively references to the procurator fiscal and to expenses.

Part IV

Pharmacies

Persons lawfully conducting retail pharmacy business

69. General provisions.

(1) Subject to the provisions of any order made under section 73 of this Act, a person carrying on a retail pharmacy business shall be taken to be a person lawfully conducting such a business if, not being disqualified by virtue of section 80 of this Act,—

(a) that person (or, if the business is carried on by a partnership, each, or, in Scotland, one or more, of the partners) is a pharmacist and the conditions specified in section 70 of this Act are fulfilled in relation to the business, or

(b) that person is a body corporate and the conditions specified in section 71 of this Act are fulfilled in relation to the business, or

(c) that person is a representative of a pharmacist (as defined by section 72 of this Act) and the conditions specified in subsection (2) of that section are fulfilled in relation to him and in relation to the business and the period applicable in accordance with subsection (3) of that section has not expired.

(1ZA) In subsection (1)(a) "pharmacist" does not include a person registered in …. Part 4 of the register maintained under article 19 of the Pharmacy Order 2010 (visiting pharmacists from relevant European States).

(2) For the purposes of the application of this Part of this Act to a business which—

(a) is or is to be carried on in one or more separate or distinct parts (but not the whole) of a building, whether it is or is to be also carried on elsewhere or not, or

(b) so far as concerns the retail sale of medicinal products, or the supply of such products in circumstances corresponding to retail sale, is or is to be carried on in one or more separate or distinct parts (but not the whole) of a building, whether it is or is to be carried on elsewhere or not,

each such part of that building shall be taken to be separate premises.

(3) In this Part of this Act—

…

"the board", in relation to a body corporate, means the body of persons controlling the body corporate, by whatever name called;

….

"the register" means –

(a) in relation to Great Britain, the register established and maintained under article 19 of the Pharmacy Order 2010; and

(b) in relation to Northern Ireland, the register kept for the purposes of section 75;

"the registrar" means –

(a) in relation to Great Britain, the person appointed under article 18 of the Pharmacy Order 2010 as registrar for the purposes of that Order; and

(b) in relation to Northern Ireland, the person appointed under Article 9(1) of the Pharmacy (Northern Ireland) Order 1976 as registrar for the purposes of that Order;

"the relevant disciplinary committee" means –

(a) in relation to Great Britain, the Fitness to Practice Committee established under article 4(6) of the Pharmacy Order 2010; and

(b) in relation to Northern Ireland, the Statutory Committee appointed under article 19 of the Pharmacy (Northern Ireland) Order 1976;

"relevant European State" means either an EEA State other than the United Kingdom or Switzerland;

70. Business carried on by individual pharmacist or by partners

(1) The conditions referred to in section 69(1)(a) of this Act are that subsections (2) and (3) of this section are both satisfied as respects each of the premises where the retail pharmacy business is carried on and medicinal products, other than medicinal products on a general sale list, are sold by retail.

(2) This subsection is satisfied if a responsible pharmacist who satisfies the requirements of subsections (4) and (5) of this section is in charge of the business at those premises, so far as concerns—

(a) the retail sale at those premises of medicinal products (whether they are on a general sale list or not), and

(b) the supply at those premises of such products in circumstances corresponding to retail sale.

(3) This subsection is satisfied if a notice is conspicuously displayed at those premises stating—

(a) the name of the responsible pharmacist for the time being,

(b) the number of his registration under the Part 4 of the Pharmacy Order 2010 or, in relation to Northern Ireland, the Pharmacy (Northern Ireland) Order 1976, and

(c) the fact that he is for the time being in charge of the business at those premises.

(4) The responsible pharmacist must be—

(a) the person carrying on the business, or

(b) if the business is carried on by a partnership, one of the partners or, in Scotland, one of the partners who is a person registered in Part 1 of the Register of Pharmacists maintained under article 19 of the Pharmacy Order 2010 (pharmacists other than visiting practitioners), or

(c) another pharmacist.

(5) In relation to premises in Great Britain that have been registered pharmacies for less than three years, the responsible pharmacist may not be a person who is a pharmacist by virtue of a qualification in pharmacy awarded in a relevant European State.

(6) Subsection (5) does not apply to premises entered in the register by virtue of section 74J.

71. Business carried on by body corporate

(1) The conditions referred to in section 69(1)(b) of this Act are—

(a) that the retail pharmacy business, so far as concerns the keeping, preparing and dispensing of medicinal products other than medicinal products on a general sale list, is under the management of a superintendent in respect of whom the requirements specified in subsection (6) of this section are fulfilled, and

(b) that subsections (2) and (3) of this section are both satisfied as respects each of the premises where the business is carried on and medicinal products, other than medicinal products on a general sale list, are sold by retail.

(2) This subsection is satisfied if a responsible pharmacist who satisfies the requirements of subsections (4) and (5) of this section is in charge of the business at the premises mentioned in subsection (1)(b) of this section, so far as concerns—

(a) the retail sale at those premises of medicinal products (whether they are on a general sale list or not), and

(b) the supply at those premises of such products in circumstances corresponding to retail sale.

(3) This subsection is satisfied if a notice is conspicuously displayed at those premises stating—

(a) the name of the responsible pharmacist for the time being,

(b) the number of his registration under Part 4 of the Pharmacy Order 2010 or, in relation to Northern Ireland, the Pharmacy (Northern Ireland) Order 1976, and

(c) the fact that he is for the time being in charge of the business at those premises.

(4) The responsible pharmacist must be—

(a) the superintendent mentioned in subsection (1)(a) of this section, or

(b) a manager or assistant subject to the directions of the superintendent and who is a pharmacist.

(5) In relation to premises in Great Britain that have been registered pharmacies for less than three years, the responsible pharmacist may not be a person who is a pharmacist by virtue of a qualification in pharmacy awarded in a relevant European State.

(5A) Subsection (5) does not apply to premises entered in the register by virtue of section 74J.

(6) The requirements referred to in subsection (1)(a) of this section in relation to a superintendent are that—

(a) he is a pharmacist,

(b) a statement in writing signed by him, and signed on behalf of the body corporate, specifying his name and stating whether he is a member of the board of that body or not, has been sent to the registrar, and

(c) he does not act in a similar capacity for any other body corporate.

(7) In subsection (6)(a) “pharmacist” –

(a) does not include a person registered in Part 4 of the register maintained under article 19 of the Pharmacy Order 2010 (visiting pharmacists from relevant European States) unless the retail pharmacy business under the management of the person is carried on (in whole or in part) at premises entered in the register by virtue of section 74J; and

(b) does not in clued a person registered in the register of visiting pharmaceutical chemists from relevant European States maintained under article 9 of the Pharmacy (Northern Ireland) Order 1976.

(8) If a person who has managed a relevant retail pharmacy business as a superintendent ceases to do so (otherwise than by reason of death) the person must notify the registrar in writing of the fact within the period of 28 days beginning with the day on which the person ceases to manage the business.

(9) For the purposes of subsection (8) "a relevant retail pharmacy business" is a retail pharmacy business carried on (in whole or in part) at premises in Great Britain.

72. Representative of pharmacist in case of death or disability.

(1) The provisions of this section shall have effect where a pharmacist carries on a retail pharmacy business and—

(a) he dies, or

(b) he is adjudged bankrupt or enters into a composition or scheme or deed of arrangement with his creditors, or, in Scotland, sequestration of his estate is awarded or he makes a trust deed for behoof of his creditors or a composition contract, or

(c) a receiver is appointed for him under Part VIII of the Mental Health Act 1959, or, in Scotland, a guardian or judicial factor is appointed for him on the ground that he suffers from mental disorder, or, in Northern Ireland, a committee, receiver or guardian is appointed in his case under the Lunacy Regulation (Ireland) Act 1871, and a representative of his thereafter carries on his business.

(2) The conditions referred to in section 69(1)(c) of this Act are—

(a) that the name and address of the representative, and the name of the pharmacist whose representative he is, have been notified to the registrar, and

(b) that subsections (2A) and (2B) of this section are both satisfied as respects each of the premises at which the business is carried on and medicinal products, other than medicinal products on a general sale list, are sold by retail.

(2A) This subsection is satisfied if a responsible pharmacist is in charge of the business at the premises mentioned in subsection (2)(b) of this section, so far as concerns—

(a) the retail sale at those premises of medicinal products (whether they are on a general sale list or not), and

(b) the supply at those premises of such products in circumstances corresponding to retail sale.

(2B) This subsection is satisfied if a notice is conspicuously displayed at those premises stating—

(a) the name of the responsible pharmacist for the time being,

(b) the number of his registration under Part 4 of the Pharmacy Order 2010 or, in relation to Northern Ireland, the Pharmacy (Northern Ireland) Order 1976, and

(c) the fact that he is for the time being in charge of the business at those premises.

(3) The period referred to in section 69(1)(c) of this Act—

(a) in the case of the death of a pharmacist, is a period of five years from the date of his death;

(b) in the case of the bankruptcy or sequestration of the estate of a pharmacist, is a period of three years from the date on which he is adjudged bankrupt or the date of the award of sequestration, as the case may be;

(c) in the case of a composition or scheme or deed of arrangement, or of a trust deed or composition contract, is a period of three years from the date on which the trustee appointed thereunder becomes entitled to carry on the business; and

(d) in a case falling within subsection (1)(c) of this section, is a period of three years from the date of the appointment of the receiver, curator bonis, judicial factor, committee or guardian,

or, in any such case, is such longer period as, on the application of the representative, the relevant disciplinary committee, having regard to all the circumstances of the case, may direct.

(4) In this section "representative"—

(a) in relation to a pharmacist who has died, means his executor or administrator and, in respect of a period of three months from the date of his death, if he has died leaving no executor who is entitled and willing to carry on the business, includes any person beneficially interested in his estate;

(b) in a case falling within paragraph (*b*) of subsection (1) of this section, means the trustee in bankruptcy or the trustee in the sequestration or any trustee appointed under the composition scheme, deed of arrangement, trust deed or composition contract; and

(c) in a case falling within paragraph (*c*) of that subsection, means the receiver, curator bonis, judicial factor, committee or guardian; and in paragraph (*b*) above the reference to a trustee appointed under a composition, scheme or deed of arrangement includes a reference to the supervisor of a voluntary arrangement proposed for the purposes of, and approved under, Part VIII of the Insolvency Act 1986 or Chapter II of Part VIII of the Insolvency (Northern Ireland) Order 1989.

72A The responsible pharmacist

(1) It is the duty of the responsible pharmacist mentioned in sections 70, 71 and 72 of this Act to secure the safe and effective running of the pharmacy business at the premises in question so far as concerns—

(a) the retail sale at those premises of medicinal products (whether they are on a general sale list or not), and

(b) the supply at those premises of such products in circumstances corresponding to retail sale.

(2) A person may not be the responsible pharmacist in respect of more than one set of premises at the same time, except in circumstances specified by the … Ministers in regulations, and then only if such conditions as may be so specified are complied with.

(3) The responsible pharmacist must establish (if they are not already established), maintain and keep under review procedures designed to secure the safe and effective running of the business as mentioned in subsection (1) of this section.

(4) The responsible pharmacist must make a record (which must be available at the premises) of—

(a) who the responsible pharmacist is in relation to the premises on any day and at any time, and

(b) such other matters as the … Ministers specify in regulations.

(5) It is the duty of the person carrying on the business to secure that—

(a) the record is properly maintained, and

(b) it is preserved for at least as long as is specified in regulations made by the … Ministers.

(6) The … Ministers may make further provision in regulations in relation to the responsible pharmacist.

(7) The regulations may, in particular, make further provision about the matters mentioned in subsections (1) to (4) of this section, and make provision about—

(a) the qualifications and experience which a person must have if he is to be a responsible pharmacist,

(b) the responsible pharmacist's absence from the premises,

(c) the supervision by the responsible pharmacist, when he is not present on the premises, of relevant activities there,

(d) circumstances in which the responsible pharmacist may supervise relevant activities at a pharmacy of which he is not the responsible pharmacist,

(e) the form in which the procedures referred to in subsection (3) of this section are to be recorded and matters which must be covered by them,

(f) the form in which the record referred to in subsection (4) of this section is to be kept and particulars which must be included in it.

(8) In subsection (7)(c) and (d), "relevant activities" means things mentioned in section 10 and transactions mentioned in section 52(1)(c) of this Act.

72B Section 72A: supplementary

(1) The failure by a person to comply with any requirements of section 72A of this Act, or of regulations made under that section, may constitute misconduct for the purposes of section 80 of this Act, article 51(1)(a) of the Pharmacy Order 2010 and Article 20 of the Pharmacy (Northern Ireland) Order 1976; and the relevant disciplinary committee may deal with such a failure accordingly.

(2) A person who does not have the qualifications and experience required by regulations made by virtue of section 72A(7)(a) of this Act is not to be considered as a responsible pharmacist for the purposes of sections 70 to 72 of this Act.

(3) Subsection (4) of this section applies if a person—

(a) fails to comply with the requirements of subsection (2) of section 72A of this Act, or of regulations made under that subsection,

(b) fails to comply with any requirements as to absence from the premises contained in regulations made by virtue of subsection (7)(b) of that section.

(4) If this subsection applies, the person in question is not to be considered while the failure continues as being in charge of the business at the premises in question (or in a subsection (3)(a) case at any of them) for the purposes of sections 70 to 72 of this Act.

73. Power to extend or modify conditions.

(1) The … Ministers may by order add to, revoke or vary any of the provisions of sections 70 to 72 of this Act, so as either—

(a) to modify, or provide new conditions in substitution for, the conditions referred to in any of the paragraphs of section 69(1) of this Act, or

(b) for the purposes of any of those paragraphs, to provide alternative conditions compliance with which is to have the like effect as compliance with the conditions referred to in that paragraph.

(2) Any provision made by an order in accordance with subsection (1) of this section may be made either generally or in relation to any particular circumstances specified in the order.

(3) Any order made under this section may direct that subsection (1) or subsection (2) of section 69 of this Act shall have effect subject to such exceptions or modifications as appear to the … Ministers to be necessary or expedient in consequence of the provision made by the order in accordance with subsection (1) of this section.

(4) Where an order under this section is for the time being in force, any reference to section 69 of this Act in any other enactment as amended by this Act shall be construed as a reference to that section as modified by the order.

(5) No order shall be made under this section unless a draft of the order has been laid before Parliament and approved by a resolution of each House of Parliament.

Registration of pharmacies

74. Meaning of "registered pharmacy".

(1) . . . In this Act "registered pharmacy" means premises for the time being entered in the register.

(1A) If the entry of a registered pharmacy in the register is suspended under paragraph (4)(b) of the Pharmacy Order 2010 then, except for such purposes of that Order as the General Pharmaceutical Council may prescribe by rules, that registered pharmacy must be treated as not being entered in the register notwithstanding that the register still includes the address of that pharmacy.

(1B) Accordingly, premises whose entry in the register is suspended are not to be treated as a registered pharmacy for the purposes of this Act or any other enactment apart from that Order.

(2) . . . .

(3) …`

(4) . . . .

74A. Registration of premises: Great Britain

(1) This section applies in relation to premises in Great Britain.

(2) If the registrar is satisfied that the conditions in section 74B are met in relation to premises that are not entered in the register, the registrar must enter the premises in Part 3 of the register unless the registrar considers that doing so would prejudice the health, safety or well-being of members of the public.

(3) Subject to subsection (5) and to section 74H, the entry of premises entered in Part 3 of the register under subsection (2) is valid for the period of one year beginning with the date on which the entry was made.

(4) If the registrar is satisfied that the conditions in section 74B are met in relation to premises entered in Part 3 of the register under subsection (2), the registrar must renew the entry of the premises unless the registrar considers that doing so would prejudice the health, safety or well-being of members of the public.

(5) Subject to subsection (7) and to section 74H, each renewal of the entry of premises entered in Part 3 of the register under subsection (2) extends the validity of the entry for the period of one year beginning with the day on which the entry would otherwise have ceased to be valid.

(6) The registrar may, except in such circumstances as may be prescribed by the General Pharmaceutical Council in rules, renew the entry of premises in Part 3 of the register for a period exceeding one year beginning with the day on which the entry would otherwise have ceased to be valid in which case the renewal of the entry of premises entered in that part of the register under subsection (2) extends the validity of the entry for that period.

(7) If the entry of premises entered in Part 3 of the register under this section ceases to be valid then, except in such circumstances as may be prescribed by the General Pharmaceutical Council in rules, the premises are to be treated for all purposes as no longer being entered in Part 3 of the register and accordingly the registrar must remove the entry from that part of the register.

74B. Conditions for registration: Great Britain

(1) The conditions referred to in section 74A are as follows.

(2) Condition A is that an application for the entry of the premises in Part 3 of the register or, as the case may be, for the renewal of the entry of the premises in Part 3 of the register is made—

(a) in such form and manner as is prescribed in rules made by the General Pharmaceutical Council; and

(b) if the application is an application for renewal, by such time prior to the entry ceasing to be valid as is so prescribed.

(3) Condition B is that the appropriate fee prescribed in rules made by the General Pharmaceutical Council under article 36(1) of the Pharmacy Order 2010 is paid.

(4) Condition C—

(a) if the application is an application for the entry of the premises in Part 3 of the register, is that either—

(i) the applicant is lawfully conducting a retail pharmacy business, or

(ii) if the premises are entered in Part 3 of the register, and the applicant begins to carry on a retail pharmacy business at the premises, the applicant will, from the time the applicant begins to do so, be a person lawfully conducting a retail pharmacy business; or

(b) if the application is an application for the renewal of the entry of the premises in Part 3 of the register, is that the applicant is lawfully conducting a retail pharmacy business at the premises.

(5) Condition D—

(a) if the application is an application for the entry of the premises in Part 3 of the register, is that the standards that are provided for in rules made under article 7(1) of the Pharmacy Order 2010 are met, or are capable of being met, in connection with the carrying on of a retail pharmacy business at the premises; or

(b) if the application is an application for the renewal of the entry of the premises in Part 3 of the register, is—

(i) that the standards that are provided for in rules made under article 7(1) of the Pharmacy Order 2010 are met in connection with the carrying on of a retail pharmacy business at the premises, and

(ii) that the requirements of rules made under article 7(4) of that Order are met by the person carrying on a retail pharmacy business at the premises.

74C. Supplementary provision in respect of registration of premises: Great Britain

(1) The registrar may restore to Part 3 of the register the entry of premises removed from that part of the register by virtue of section 74A(7) if an application is made to the registrar in accordance with this section.

(2) An entry restored under this section to Part 3 of the register—

(a) is still to be treated as having been entered in that part of the register under section 74A;

(b) is valid for the period of one year beginning with the day on which the entry would otherwise have ceased to be valid by virtue of section 74A(7) or is valid for such longer period beginning with that day as the registrar may in any particular case allow; and

(c) may be subject to the same conditions as those to which the entry was subject immediately before it was removed from Part 3 of the register by virtue of section 74A(7) or may be subject to such other conditions as the registrar may impose under section 74D(1).

(3) An application for restoration may be made to the registrar by the person who is the owner of the retail pharmacy business previously carried on at the premises and that person must be—

(a) a person who is lawfully conducting a retail pharmacy business; or

(b) a person who, if the entry of the premises is restored to Part 3 of the register and the person begins to carry on a retail pharmacy business at the premises, will, from the time the person begins to do so, be a person lawfully conducting a retail pharmacy business.

(4) The General Pharmaceutical Council may make rules in connection with applications under this section.

(5) Rules under subsection (4) may, in particular, include provision—

(a) about the form and manner in which applications are to be made (and the rules may provide that applicants must apply using application forms that are in such form as the General Pharmaceutical Council may determine from time to time);

(b) about the information to be provided in respect of applications; and 80

(c) about the circumstances in which applications must or, as the case may be, may be refused (including where an application for renewal under this section was not received by the registrar by the time prescribed by the General Pharmaceutical Council in rules under section 74B(2)(b)).

(6) Where the registrar restores the entry of premises to Part 3 of the register pursuant to an application under this section, the registrar must give notice in writing of that restoration to the applicant.

(7) The notice under subsection (6) must specify—

(a) the period for which the entry restored to Part 3 of the register is valid;

(b) any conditions to which that entry is subject by virtue of subsection (2)(c).

(8) The notice under subsection (6) must be sent—

(a) where the retail pharmacy business was carried on by an individual, to that individual at that individual's home address in the register;

(b) where the retail pharmacy business was carried on by a partnership, to that partnership at its principal office;

(c) where the retail pharmacy business was carried on by a body corporate, to that body corporate at its registered or principal office.

74D.Conditional registration: Great Britain

(1) The registrar may make the entry of premises entered in Part 3 of the register under section 74A subject to such conditions as the registrar considers it necessary to impose for the purpose of securing the safe and effective practice of pharmacy at those premises.

(2) The power under subsection (1)—

(a) may be exercised on the making of the entry or subsequently (whether on a renewal of the entry or otherwise);

(b) includes power to vary the conditions to which the entry of the premises in Part 3 of the register is subject, including by adding to the conditions or revoking any of them.

(3) Except as provided in subsection (4), the registrar may not under subsection (1)—

(a) impose a new condition in respect of premises already entered in Part 3 of the register; or

(b) vary or revoke any conditions to which the entry of premises entered in Part 3 of the register is subject,

unless the registrar has given reasonable notice in writing of the condition to be imposed or, as the case may be, of the variation or revocation of an existing condition, to the person carrying on the retail pharmacy business at the premises and of the date from which that condition, variation or revocation is to have effect.

(4) The registrar may, with immediate effect—

(a) impose a new condition in respect of premises already entered in Part 3 of the register; or

(b) vary or revoke any conditions to which the entry of premises entered in Part 3 of the register is subject,

if, in the registrar's opinion, the giving of reasonable notice as required by subsection (3)would prejudice the health, safety or well-being of members of the public.

(5) The registrar must give notice in writing of any decision under subsection (4) to the person carrying on a retail pharmacy business at the premises.

(6) The notice under subsection (5) must be sent—

(a) where the retail pharmacy business is carried on by an individual, to that individual at that individual's home address in the register;

(b) where the retail pharmacy business is carried on by a partnership, to that partnership at its principal office; or

(c) where the retail pharmacy business is carried on by a body corporate, to that body corporate at its registered or principal office.

(7) Where premises are entered in the register because condition C in section 74B is met by virtue of subsection (4)(a)(ii) of that section, the registrar may, on making the entry of the premises in the register, also make that entry subject to a condition that the applicant for registration will be a person lawfully conducting a retail pharmacy business within such period as the registrar reasonably determines beginning with the date on which the entry is made.

74E. Supplementary provision in respect of conditional registration: Great Britain

(1) Where the entry of premises entered in Part 3 of the register is subject to conditions imposed under section 74D(1), the person carrying on the business at the premises may apply to the registrar for any of the conditions imposed to be varied or revoked.

(2) The General Pharmaceutical Council may make rules in connection with applications under subsection (1).

(3) Rules under subsection (2) may, in particular, include provision—

(a) about the form and manner in which applications are to be made (and the rules may provide that applicants must apply using application forms that are in such form as the General Pharmaceutical Council may determine from time to time);

(b) about the information to be provided in respect of applications;

(c) about the circumstances in which applications may be refused by the registrar;

(d) about the giving of notice of the decision in respect of the application to the applicant by the registrar.

(4) The registrar may vary a condition imposed under section 74D(7) by extending the period within which the applicant for registration must become a person lawfully conducting a retail pharmacy business.

(5) Where premises are entered in the register subject to a condition imposed under subsection (7) of section 74D, the registrar may remove the entry if the applicant is not a person lawfully conducting a retail pharmacy business at the premises within the period determined by the registrar in accordance with that subsection or within such longer period as the registrar may, by virtue of subsection (4), allow.

(6) Where the registrar—

(a) varies a condition under subsection (5); or

(b) removes an entry of premises in Part 3 of the register under subsection (4),

the registrar must send to the person who applied for registration a statement in writing giving that person notice of the decision and the reasons for it.

(7) The notice under subsection (6) must be sent—

(a) where the person who applied for registration is an individual, to that individual at that individual's home address in the register;

(b) where that person is a partnership, to that partnership at its principal office;

(c) where that person is a body corporate, to that body corporate at its registered or principal office.

74F. Giving of notice by registrar: Great Britain

(1) Where, in pursuance of an application, the registrar enters premises in Part 3 of the register under section 74A, the registrar must give to the applicant a written confirmation of the entry.

(2) The written confirmation under subsection (1) must include—

(a) the number of the entry;

(b) the date on which the entry was made;

(c) the period for which the entry is valid; and

(d) details of any conditions to which the entry is subject by virtue of section 74D.

(3) Where, in pursuance of an application, the registrar renews the entry of premises in Part 3 of the register under section 74A, the registrar must give to the applicant a written confirmation of the renewal.

(4) The written confirmation under subsection (3) must include—

(a) the number of the entry;

(b) the date on which the renewal of the entry was made;

(c) the period for which the renewal of the entry is valid; and

(d) details of any conditions to which the renewal of the entry is subject by virtue of section 74D.

(5) Where the registrar refuses an application for the entry of premises in Part 3 of the register under section 74A, or for the renewal of an entry of premises in the register under that section, the registrar must give to the applicant written notice of that refusal and the reasons for it and of the right of appeal to the Appeals Committee under article 40 of the Pharmacy Order 2010.

(6) Where, under section 74J, the registrar enters premises or a group of premises in Part 3 of the register, the registrar must give written confirmation of the entry to the person who will be carrying on a retail pharmacy business at the premises, or at each set of premises in the group of premises.

(7) The written confirmation under subsection (6) must include—

(a) the number of the entry;

(b) the date on which the entry was made; and

(c) details of any conditions to which the entry is subject by virtue of section 74J(4).

74G. Voluntary removal from the register: Great Britain

(1) An application may be made to the registrar by the person carrying on a retail pharmacy business at any premises entered in Part 3 of the register under section 74A or 74J for the premises to be removed from the register.

(2) The General Pharmaceutical Council may make rules in connection with applications under subsection (1).

(3) Rules under subsection (2) may, in particular, include provision—

(a) about the form and manner in which applications are to be made (and the rules may provide that applicants must apply using application forms that are in such form as the Council may determine from time to time);

(b) about the information to be provided by the applicant;

(c) about the circumstances in which applications may be refused; and

(d) for written notice of the outcome of the application to be given to the applicant by the registrar.

74H. Change of ownership of retail pharmacy business: Great Britain

(1) Subject to subsection (2), where a change occurs in the ownership of a retail pharmacy business carried on at premises entered in Part 3 of the register under section 74A, the entry of the premises in the register ceases to be valid at the end of the relevant period unless the registrar

is notified in writing of the change prior to the end of the relevant period by the person who, as a result of the change, will be the person carrying on the business at the premises.

(2) Subsection (1) only applies if the relevant period is shorter than the period for which the entry would otherwise have remained valid under section 74A.

(3) Where, before the end of the relevant period, the registrar is notified of a change in the ownership of a retail pharmacy business carried on at premises entered in Part 3 of the register, the registrar must, on receipt of a fee of the amount prescribed in rules under article 36(1)(c) of the Pharmacy Order 2010, amend the entry relating to the premises in Part 3 of the Register to record the name and address of the person who, as a result of the change, will be the person carrying on the retail pharmacy business at the premises.

(4) For the purposes of subsections (1) to (3), the relevant period—

(a) if the change occurs on the death of the person carrying on the business or, in the case of a partnership, on the death of one of the partners, the period of three months beginning with the date of death; and

(b) in any other case, the period of 28 days beginning with the date on which the change occurred.

(5) If the entry of premises entered in Part 3 of the register under section 74A ceases to be valid under this section, the premises are to be treated for all purposes as no longer being entered in the register and accordingly the registrar must remove the entry from the register.

(6) The registrar must restore the entry of the premises to Part 3 of the register if—

(a) an application for restoration is made to the registrar in accordance with section 74I(1) and with rules made under section 74I(3);

(b) a fee of an amount prescribed in rules under article 36(1)(b) of the Pharmacy Order 2010 (fees in connection with entry) is paid; and

(c) the registrar is satisfied that the standards that are provided for in rules made under article 7(1) of the Pharmacy Order 2010 are met in connection with the carrying on of a retail pharmacy business at the premises.

(7) Subject to subsection (8), an entry restored to the register under subsection (6)—

(a) is still to be treated as having been entered in Part 3 of the register under section 74A;

(b) is subject to the same conditions as those to which the entry was subject immediately before it was removed from Part 3 of the register by virtue of subsection (5);

(c) is valid for the same period as the period for which the entry would have been valid under section 74A had it not been removed from Part 3 of the register by virtue of subsection (5) of this section.

(8) Where an entry of premises in Part 3 of the register is restored by the registrar under subsection (6) and the applicant is a person falling within section 74I(2)(b), the registrar may—

(a) on restoring the entry of the premises to the register, make that entry subject to a condition that the applicant for restoration will be a person lawfully conducting a retail pharmacy business within such period as the registrar reasonably determines beginning with the date on which the entry is restored; and

(b) subsequently remove the entry of the premises from Part 3 of the register if the applicant is not a person lawfully conducting a retail pharmacy business within the period determined by the registrar in accordance with paragraph (a).

(9) Where under subsection (8)(b) the registrar removes an entry of premises from Part 3 of the register, the registrar must give to the person who was carrying on a retail pharmacy business at the premises immediately prior to the removal written notice of the removal and the reasons for it.

(10) The notice under subsection (9) must be sent—

(a) where the retail pharmacy business is carried on by an individual, to that individual at that individual's home address in the register;

(b) where the retail pharmacy business is carried on by a partnership, to the principal office of that partnership;

(c) where the retail pharmacy business is carried on by a body corporate, to the registered or principal office of that body corporate.

74I. Supplementary provision in respect of change of ownership of retail pharmacy business: Great Britain

(1) An application may be made to the registrar for the entry of premises removed from Part 3 of the register by virtue of section 74H(5) to be restored to the register.

(2) An application under subsection (1) must be made by the person who, in consequence of the change of ownership, has become the owner of the business and that person must be—

(a) a person who is lawfully conducting a retail pharmacy business; or

(b) a person who, if the entry of the premises is restored to Part 3 of the register and the person begins to carry on a retail pharmacy business at those premises, will, from the time the person begins to do so, be a person lawfully conducting a retail pharmacy business.

(3) The General Pharmaceutical Council may make rules in connection with applications under subsection (1).

(4) Rules under subsection (3) may, in particular, include provision—

(a) about the form and manner in which applications are to be made (and the rules may provide that applicants must apply using application forms that are in such form as the Council may determine from time to time);

(b) about the information to be provided in respect of applications;

(c) about the circumstances in which an application for restoration under subsection (1) may be treated by the registrar as an application for the renewal of registration under section 74A(4) as well as an application for restoration.

(5) Where the registrar restores the entry of premises to Part 3 of the register pursuant to an application under subsection (1), the registrar must send to the applicant for restoration a statement in writing giving the applicant notice of the restoration.

(6) The notice given by the registrar under subsection (5) must specify—

(a) the period for which the entry restored to Part 3 of the register is valid;

(b) any conditions to which the entry of the premises restored to Part 3 of the register is subject.

(7) Where the registrar refuses an application under this section for the restoration to Part 3 of the register of an entry relating to any premises, the registrar must send to the applicant for restoration a statement in writing giving the applicant notice of the decision and the reasons for it.

(8) The notice under subsections (5) and (7) must be sent—

(a) where the applicant is an individual, to that individual at that individual's home address in the register;

(b) where the applicant is a partnership, to the principal office of that partnership;

(c) where the applicant is a body corporate, to the registered or principal office of that body corporate.

74J. Temporary registration with regard to emergencies involving loss of human life or human illness etc.

(1) This section applies in relation to premises in Great Britain.

(2) If the Secretary of State advises the registrar that an emergency has occurred, is occurring or is about to occur and that action should be considered under this section, the registrar may under this section enter in Part 3 of the register—

(a) premises; or

(b) premises comprising a specified group of premises,

with regard to the emergency.

(3) The registrar may enter in Part 3 of the register by virtue of subsection (2)(b) all of the premises in a specified group of premises without first identifying each set of premises in the group.

(4) The registrar may make the entry of premises entered in Part 3 of the register under this section subject to such conditions as the registrar considers necessary to impose for the purpose of securing the safe and effective practice of pharmacy at those premises.

(5) The power in subsection (4)—

(a) may be exercised on the making of the entry or subsequently;

(b) includes power to vary the conditions to which the entry of the premises in Part 3 of the register is subject, including by adding to the conditions or revoking any of them.

(6) The entry of premises entered in Part 3 of the register under this section by virtue of subsection (2)(b) as one of a specified group may be subject to the same conditions as the entry of the other premises in the group or it may be subject to different conditions.

(7) The conditions to which the entry of premises entered in Part 3 of the register under this section is subject may include conditions relating to their physical state, safety and security and the conditions in which medicinal products (including controlled drugs) are stored at those premises.

(8) The registrar may not under subsection (4)—

(a) impose a new condition in respect of the entry of premises already entered in Part 3 of the register; or

(b) vary or revoke any conditions to which the entry of premises entered in Part 3 of the register is subject,

unless the registrar has given reasonable notice in writing of the condition to be imposed or, as the case may be, of the variation or revocation of an existing condition, to the person carrying on a retail pharmacy business at the premises and of the date from which that condition, variation or revocation is to have effect.

(9) The entry of premises entered in Part 3 of the register under this section may be removed by the registrar, which—

(a) the registrar must do if the Secretary of State advises the registrar that the circumstances that led the Secretary of State to advise the registrar as mentioned in subsection (2) no longer exist;

(b) the registrar may do for any other reason at any time including where the registrar has grounds for suspecting that there is a failure to comply with any conditions to which the entry of the premises in Part 3 of the register is subject.

(10) The entry of premises entered in Part 3 of the register under this section by virtue of subsection (2)(b) as one of a specified group of premises may be removed without removing the entries of the other premises in the group, or it may be removed by virtue of a decision to remove the entries of all of the premises in the group.

(11) In this section, and in section 74K, "emergency" means an emergency of the type described in subsection (1)(a) of section 19 of the Civil Contingencies Act 2004 (meaning of "emergency"), read with subsection (2)(a) and (b) of that section.

74K. Temporary annotations with regard to emergencies involving loss of human life or human illness etc.

(1) If the Secretary of State advises the registrar that an emergency has occurred, is occurring or is about to occur and that action should be considered under this section, the registrar may annotate—

(a) the entry of a registered pharmacy entered in Part 3 of the register under section 74J to designate that pharmacy as a pharmacy from which drugs, medicines and appliances may be ordered in a specified capacity; or

(b) the entries of a specified group of registered pharmacies entered in Part 3 of the register under section 74J to designate that group as a group of pharmacies from which drugs, medicines and appliances may be ordered in a specified capacity.

(2) The registrar may make an annotation, by virtue of subsection (1), to the entry of a registered pharmacy entered in Part 3 of the register under section 74J in such a way as to distinguish that annotation from an annotation in respect of a registered pharmacy made otherwise than by virtue of subsection (1).

(3) Annotations made by virtue of subsection (1)—

(a) must be removed by the registrar if the Secretary of State advises the registrar that the circumstances that led the Secretary of State to advise the registrar as mentioned in subsection (1) no longer exist;

(b) may be removed by the registrar for any other reason at any time.

(4) An annotation of the entry of a registered pharmacy made by virtue of subsection (1)(b) as one of a specified group may be removed without removing the annotations of the entries of the other registered pharmacies in the group, or it may be removed by virtue of a decision to remove the annotations of the entries of all the registered pharmacies in the group.

Evidence of registration: Great Britain

74L. A document purporting to be a certificate signed by the registrar and stating that, on a specified date, specified premises in Great Britain were, or were not, entered in Part 3 of the register (whether under section 74A or section 74J) is admissible in any proceedings as evidence (or in Scotland, as sufficient evidence) that those premises were, or were not, entered in the register on that date.

75. Registration of premises: Northern Ireland.

(A1) This section applies in relation to premises in Northern Ireland.

(1) It shall be the duty of the registrar to keep a register for the purposes of this section and, subject to the following provisions of this section, on payment of the prescribed fee to enter in the register any premises in respect of which an application is made under this section.

(2) Any application for the registration of premises under this section shall be made in the prescribed manner and shall specify the premises to which the application relates and shall contain such other particulars as may be prescribed.

(3) On the making of any such application the registrar shall notify the appropriate Minister, specifying the premises to which the application relates and the date on which the application was made, and shall not enter those premises in the register before the end of the period of two months from that date, unless before the end of that period the appropriate Minister consents to his doing so.

(4) If it appears to the appropriate Minister that in a material respect the premises do not comply with the requirements of regulations made under section 66 of this Act which are for the time being in force, and accordingly he proposes to certify that the premises are unsuitable for registration under this section, he shall, before the end of the period referred to in subsection (3) of this section, serve on the applicant a notice stating his proposals and the reasons for them, and shall serve a copy of that notice on the registrar; and, where a copy of such a notice is served on him, the registrar shall not enter the premises in the register except where required to do so in accordance with the following provisions of this section.

(5) If, within the time allowed after the service on him of a notice under subsection (4) of this section, the applicant gives notice to the appropriate Minister of his desire to be heard with respect to the proposals, or makes representations in writing to the appropriate Minister with respect to the proposals, then, before determining whether to issue a certificate under this section in respect of the premises,—

(a) if the applicant has given notice of his desire to be heard, the appropriate Minister shall afford to him an opportunity of appearing before, and being heard by, a person appointed by that Minister for the purpose, or

(b) if he has made representations in writing, that Minister shall consider those representations.

(6) Where the appropriate Minister has served a notice under subsection (4) of this section, then—

(a) if he determines not to issue a certificate certifying that the premises are unsuitable for registration under this section, he shall notify the applicant and the registrar of his decision and (subject to subsection (7) of this section) the registrar shall forthwith enter the premises in the register;

(b) if the appropriate Minister issues such a certificate, he shall transmit the certificate to the registrar and shall notify the applicant that he has done so, and, if so required by the applicant, shall inform him of the reasons for his decision to issue such a certificate.

(7) Notwithstanding anything in the preceding provisions of this section, the registrar shall not enter any premises in the register in pursuance of an application under this section unless it is shown to his reasonable satisfaction either—

(a) that at the time of the application the applicant is a person lawfully conducting a retail pharmacy business, or

(b) that, if the premises are entered in the register, and the applicant begins to carry on a retail pharmacy business at those premises, then as from the time when he begins to do so he will be a person lawfully conducting a retail pharmacy business.

(8) In this section “the appropriate Minister”—

(a) …

(b) …

(c) means the Minister of Health and Social Services for Northern Ireland,

and “the time allowed” means the period of twenty-eight days or such extended period as the appropriate Minister may in any particular case allow.

76. Supplementary provisions as to registration of premises: Northern Ireland.

(1) Where any premises have been entered in the register under section 75, then, in respect of each year subsequent to the year in which the premises were so entered, a further fee (in this section referred to as a “retention fee”) of the prescribed amount shall be payable by the person carrying on a retail pharmacy business at those premises.

(2) If, on demand being made to him in the prescribed manner, the person carrying on a retail pharmacy business at any premises entered in the register under section 75 fails to pay a retention fee in respect of those premises within two months from the date on which the demand is made, the appropriate Minister may direct the registrar to remove the premises from the register; but if, before the end of the year in respect of which the retention fee is payable or such longer period as in any particular case the appropriate Minister may allow, the person carrying on the business pays to the registrar the retention fee in respect of that year, together with such additional sum (if any) by way of penalty as may be prescribed,—

(a) the registrar shall restore the premises to the register, and

(b) if the appropriate Minister so directs, the restoration shall be deemed to have had effect as from the date on which the premises were removed from the register.

(3) Where a change occurs in the ownership of a retail pharmacy business carried on at any premises registered under section 75 of this Act, the registration of the premises under that section—

(a) if the change occurs on the death of the person carrying on the business, or, in the case of a partnership, on the death of one of the partners, shall become void at the end of the period of three months from the date of the death, and

(b) in any other case, shall become void at the end of the period of twenty-eight days from the date on which the change occurs.

(4) . . . . .

(5) Where the registration of any premises under section 75 of this Act in respect of a business becomes void by virtue of subsection (3) of this section, an application for the premises to be restored to the register may be made by the person who, in consequence of the change of ownership, has become the owner of the business; and where such an application is made, and it is shown to the reasonable satisfaction of the registrar either—

(a) that at the time of the application the applicant is a person lawfully conducting a retail pharmacy business, or

(b) that, if the premises are restored to the register, and the applicant thereafter carries on a retail pharmacy business at those premises, then as from the time when he begins to do so he will be a person lawfully conducting a retail pharmacy business,

and (in a case where, if the registration had not become void, a retention fee would have become payable) a fee equal to a retention fee has been paid, the registrar shall restore the premises to the register.

(6) ….

(7) A document purporting to be a certificate signed by the registrar and stating that, on a specified date, specified premises in Northern Ireland were, or were not, entered in the register shall be admissible in any proceedings as evidence … that those premises were, or were not, entered in the register on that date.

(8) ...

(9) In this section—

"the appropriate Minister" means the Minister of Health, Social Services and Public Safety for Northern Ireland;

"year" means a period of 12 months beginning with such date as the appropriate Minister may from time to time determine..

77. Annual return of premises to registrar.

Every person who carried on a retail pharmacy business at premises in Northern Ireland shall, in the month of January in each year, send to the registrar—

(a) a list of all such premises at which his business, so far as it consists of the retail sale of medicinal products, is carried on, …

(b) …

Provisions as to use of certain titles, descriptions and emblems

78. Restrictions on use of titles, descriptions and emblems.

(1) The provisions of this section shall have effect subject to section 79 of this Act.

(2) ... No person shall—

(a) take or use any of the following titles, that is to say, chemist and druggist, druggist, dispensing chemist, and dispensing druggist, or

(b) take or use the title of chemist in connection with the sale of any goods by retail or the supply of any goods in circumstances corresponding to retail sale,

unless the conditions specified in the next following subsection are fulfilled.

(3) Those conditions are—

(a) in the case of an individual, that he is a person lawfully conducting a retail pharmacy business (either alone or as a member of a partnership) and that he does not take or use the title in question in connection with any premises at which any goods are sold by retail, or are supplied in circumstances corresponding to retail sale, unless those premises are a registered pharmacy, and

(b) in the case of a body corporate, that the body is a person lawfully conducting a retail pharmacy business and that the title in question is not taken or used by that body in connection with any premises at which any goods are sold by retail, or are supplied in circumstances corresponding to retail sale, unless those premises are a registered pharmacy, and that the pharmacist who, in relation to that business, is such a superintendent as is referred to in section 71(1) of this Act is a member of the board of the body corporate.

(4) . . . No person shall, in connection with a business carried on by him which consists of or includes the retail sale of any goods, or the supply of any goods in circumstances corresponding to retail sale, use the description "pharmacy" except in respect of a registered pharmacy or in respect of the pharmaceutical department of a hospital or a health centre.

(5) A person who is not registered in the register of pharmaceutical chemists for Northern Ireland or in the register of visiting pharmaceutical chemists from a relevant European State made out and maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976 may not—

(a) take or use the title pharmaceutical chemist, pharmaceutist, pharmacist, member of the Pharmaceutical Society of Northern Ireland or Fellow of the Pharmaceutical Society of Northern Ireland; or

(b) take or use any of the titles mentioned in paragraph (a) in connection with a business carried on (whether by him or by some other person) at any premises which consists of or includes the retail sale of any goods, or the supply of any goods in circumstances corresponding to retail sale, unless those premises are a registered pharmacy or a hospital or health centre.

(5A) A person who is not registered as a pharmacist in Part 1 or 4 of the register maintained under article 19 of the Pharmacy Order 2010 may not take or use the title pharmacist or fferyllydd (its equivalent in the Welsh language) in connection with a business carried on (whether by him or by some other person) at any premises which consists of or includes the retail sale of any goods, or the supply of any goods in circumstances corresponding to retail sale, unless those premises are a registered pharmacy or a hospital or health centre.

(5B) Subsection (5) extends to Northern Ireland only; and subsection (5A) does not extend there.

(6) . . . No person shall, in connection with any business, use any title, description or emblem likely to suggest—

(a) that he possesses any qualification with respect to the sale, manufacture or assembly of medicinal products which he does not in fact possess, or

(b) that any person employed in the business possesses any such qualification which that person does not in fact possess.

(7) For the purposes of the last preceding subsection the use of the description "pharmacy", in connection with a business carried on at any premises, shall be taken to be likely to suggest that the person carrying on the business (where that person is not a body corporate) is a pharmacist and that any other person, under whose personal control the business (so far as concerns the retail sale of medicinal products or the supply of such products in circumstances corresponding to retail sale) is carried on at those premises, is also a pharmacist.

(8) Where a person is lawfully conducting a retail pharmacy business as being a representative of a pharmacist in the circumstances specified in section 69(1)(c) of this Act, subsections (5) to (7) of this section shall not have effect so as to prevent the representative from taking or using, in connection with that business, any title, description or emblem which the pharmacist himself could have used in accordance with those subsections.

79. Provision for modifying or extending restrictions under s. 78.

(1) The … Ministers may by order provide that any of the restrictions imposed by section 78 of this Act shall cease to have effect, or shall have effect subject to such exceptions as may be specified in the order.

(2) Without prejudice to the preceding subsection, regulations made by the … Ministers may (in addition to the restrictions for the time being having effect by virtue of section 78 of this Act) impose such further restrictions or other requirements with respect to the use of titles, descriptions and emblems as may be specified in the regulations.

(3) Without prejudice to the application of section 129(6) of this Act, before making any order or regulations under this section the … Ministers shall consult the General Pharmaceutical Council and the Council of the Pharmaceutical Society of Northern Ireland.

(4) Regulations made under this section shall be of no effect unless a draft of the regulations has been laid before Parliament and approved by a resolution of each House of Parliament.

Disqualification, and removal of premises from register

80. Power for relevant disciplinary committee to disqualify and direct removal from register.

(1) Where a body corporate carries on a retail pharmacy business and—

(a) that body is convicted of an offence under one of the relevant Acts;

(b) any member of the board or any officer of, or person employed by, that body is convicted of an offence, or has been guilty of misconduct, and the offence or misconduct is such as in the opinion of the relevant disciplinary committee renders him, or would if he were a pharmacist, render him unfit to be a pharmacist; or

(c) in respect of premises in Great Britain that are entered in the register as premises at which the body corporate carries on that business, there is a failure to meet the standards that are provided for in rules made under article 7(1) of the Pharmacy Order 2010 in connection with the carrying on of the business at those premises,

then, subject to the following provisions of this Part of this Act, the relevant disciplinary committee, after inquiring into the case, may direct that the body corporate is to be disqualified for the purposes of this Part of this Act.

(2) In any case falling within the preceding subsection—

(a) if the relevant disciplinary committee give a direction under that subsection, they shall direct the registrar to remove from the register all premises entered in the register as being premises at which the body corporate carries on a retail pharmacy business;

(b) if the relevant disciplinary committee do not give a direction under the preceding subsection, they may, if they think fit, direct the registrar to remove from the register all those premises, or such of them as may be specified in the direction under this paragraph.

(3) Directions under subsection (1) of this section and under paragraph (a) of the last preceding subsection, and any direction under paragraph (b) of the last preceding subsection, may, if the relevant disciplinary committee think fit, be given so as to have effect for a limited period; and in that case the registrar, at the end of that period, shall restore to the register any premises removed from it in compliance with the direction given under paragraph (a) or paragraph (b) of the last preceding subsection.

(4) Where, in any such case as is mentioned in subsection (1) of section 72 of this Act, a representative, or a person employed by a representative in the business referred to in that subsection,—

(a) is convicted of an offence, or

(b) has been guilty of misconduct,

and the offence or misconduct is such as in the opinion of the relevant disciplinary committee renders him, or would if he were a pharmacist render him, unfit to be a pharmacist, then, subject to the following provisions of this Part of this Act, the relevant disciplinary committee, after inquiring into the case, may direct that the representative shall be disqualified for the purposes of this Part of this Act.

(5) In this and the next following section "the relevant Acts" means the Pharmacy Act 1954, this Act, the Misuse of Drugs Act 1971, the Pharmacy (Northern Ireland) Order 1976, the Pharmacists and Pharmacy Technicians Order 2007 and the Pharmacy Order 2010 and "representative" has the same meaning as in section 72 of this Act.

81. Grounds for disqualification in certain cases.

(1) Unless the conditions specified in subsection (1A) are satisfied, the relevant disciplinary committee may not do any of the following—

(a) give a direction under subsection (1) of section 80 of this Act—

(i) in a case falling within paragraph (b) of that subsection, or

(ii) in a case falling within paragraph (c) of that subsection, where the failure in question is by a member of the board or any officer of, or person employed by, the body in question; or

(b) give a direction under subsection (4) of that section.

(1A) The conditions are that—

(a) one or more of the facts specified in subsection (2) are proved to the satisfaction of the relevant disciplinary committee; and

(b) the committee are of the opinion, having regard to those facts, that the board of the body corporate or, as the case may be, the representative, is to be regarded as responsible for the offence, misconduct or failure in question.

(2) The facts referred to in subsection (1A)(a) of this section are-

(a) that the offence, misconduct or failure in question was instigated or connived at by the board or by a member of the board, or by the representative, as the case may be;

(b) that, in the case of a body corporate, a member of the board, or an officer of, or person employed by, the body corporate had, at some time within the twelve months immediately preceding the date on which the offence, misconduct or failure occurred, been guilty of a similar offence or failure or of similar misconduct and that the board had, or with the exercise of reasonable care would have had, knowledge of that previous offence, misconduct or failure;

(c) that, in the case of the representative, he or a person employed by him had, at some time within twelve months before the date on which the offence or misconduct in question occurred, been guilty of a similar offence or similar misconduct and (where it was a similar offence or similar misconduct on the part of an employee) that the representative had, or with the exercise of reasonable care would have had, knowledge of that previous offence or misconduct;

(d) if the offence, misconduct or failure in question is a continuing offence or failure or is continuing misconduct, that the board, or the representative, had, or with the exercise of reasonable care would have had, knowledge of its continuance;

(e) in the case of an offence in respect of a contravention of an enactment contained in any of the relevant Acts, that the board, or the representative, had not exercised reasonable care to secure that the enactment was complied with.

82. Procedure relating to disqualification.

(1) The relevant disciplinary committee shall not give a direction under section 80 of this Act except with the assent of the chairman of the Committee.

(2) A direction under that section shall not take effect until the end of the period of three months from the date on which notice of the direction is given to the body corporate or other person to whom it relates, and, if an appeal against the direction is brought under this section, shall not take effect until that appeal has been determined or withdrawn.

(3) Where any such direction is given, the body corporate or other person to whom it relates may, at any time before the end of the period of three months specified in subsection (2) of this section, appeal against the direction to the High Court.

(4) The Pharmaceutical Society may appear as respondent on any such appeal; and, for the purpose of enabling directions to be given as to costs on any such appeal, the Pharmaceutical Society shall be deemed to be a respondent to the appeal whether they appear on the hearing of the appeal or not.

(5) On any such appeal, the High Court may give such directions in the matter as appear to the Court to be appropriate; and it shall be the duty of the relevant disciplinary committee to comply with any such directions and (where appropriate) of the registrar to make such alterations in the register as are necessary to give effect to them.

(6) No appeal shall lie from any decision of the High Court under this section.

(7) In the application of this section to Scotland, any reference to the High Court shall be construed as a reference to the Court of Session, and any reference to costs shall be construed as a reference to expenses.

(8) In the application of this section to Northern Ireland, any reference to the High Court shall be construed as a reference to a judge of the Court of Judicature of Northern Ireland.

83. Revocation of disqualification.

(1) At any time while a direction under section 80 of this Act is in force the relevant disciplinary committee, either on the application of the person to whom it relates or without any such application, may revoke the direction.

(2) If, on an application to the relevant disciplinary committee to revoke such a direction, the committee refuse to revoke it, the applicant, at any time before the end of the period of three months from the date on which notice of the refusal is given to him, may appeal to the High Court against the refusal.

(3) Subsections (4) to (6) of section 82 of this Act shall have effect in relation to any appeal under this section as they have effect in relation to appeals under that section.

(4) In the application of this section to Scotland, any reference to the High Court shall be construed as a reference to the Court of Session; and in the application of this section to Northern Ireland, any reference to the High Court shall be construed as a reference to a judge of the Court of Judicature of Judicature of Northern Ireland.

Supplementary provisions

84. Offences under Part IV.

(A1) A person who fails to comply with either of the following shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 3 on the standard scale—

(a) subsection (4) of section 72A of this Act (which requires the making of entries in a record relating to the responsible pharmacist),

(b) subsection (5) of that section (which requires the keeping and preservation of the record).

(1) Any person who contravenes section 77 of this Act shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 3 on the standard scale.

(2) Any person who contravenes section 78 of this Act or who contravenes any regulations made under section 79(2) of this Act shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 3 on the standard scale.

84A. Rules by the General Pharmaceutical Council

(1) The General Pharmaceutical Council may make such provision as it considers appropriate in rules for any purpose for which rules are authorised or required to be made by it under Part 4 of this Act.

(2) Article 66 of the Pharmacy Order 2010 (rules) applies to the making of rules by the General Pharmaceutical Council under Part 4 of this Act as it applies to the making of rules by the General Pharmaceutical Council under Part 3 of that Order (registered pharmacies: standards in retail pharmacies).

Part V

Containers, packages and identification of medicinal products

85. Labelling and marking of containers and packages.

(1) The … Ministers may make regulations imposing such requirements as, for any of the purposes specified in subsection (2) of this section, they consider necessary or expedient with respect to any of the following matters, that is to say -

(a) the labelling of containers of medicinal products;

(b) the labelling of packages of medicinal products;

(c) the display of distinctive marks on containers and packages of medicinal products.

(2) The purposes referred to in the preceding subsection are -

(a) securing that medicinal products are correctly described and readily identifiable;

(b) securing that any appropriate warning or other appropriate information or instruction is given, and that false or misleading information is not given, with respect to medicinal products;

(c) promoting safety in relation to medicinal products.

(3) No person shall, in the course of a business carried on by him, sell or supply, or have in his possession for the purpose of sale or supply, any medicinal product in such circumstances as to contravene any requirements imposed by regulations under this section which are applicable to that product.

(4) In so far as any such requirements relate to the labelling or marking of containers of medicinal products, a person who, in the course of a business carried on by him, sells or supplies a medicinal product to which the requirements are applicable without its being enclosed in a container shall, except in so far as the regulations otherwise provide, be taken to contravene those requirements as if he had sold or supplied it in a container not complying with those requirements.

(5) Without prejudice to the preceding provisions of this section, no person shall, in the course of a business carried on by him, sell or supply, or have in his possession for the purpose of sale or supply, a medicinal product of any description in a container or package which is labelled or marked in such a way that the container or package -

(a) falsely describes the product, or

(b) is likely to mislead as to the nature or quality of the product or as to the uses or effects of medicinal products of that description.

86. Leaflets.

(1) The … Ministers may make regulations imposing such requirements as, for any of the purposes specified in section 85(2) of this Act, they consider necessary or expedient with respect to leaflets relating to medicinal products which are supplied, or are intended to be supplied, with the products, whether by being enclosed in containers or packages of the products or otherwise.

(2) No person shall, in the course of a business carried on by him, supply with any medicinal product, or have in his possession for the purpose of so supplying, a leaflet which contravenes any requirements imposed by regulations under this section which are applicable to that leaflet.

(3) Without prejudice to the preceding provisions of this section, no person shall, in the course of a business carried on by him, supply with a medicinal product of any description, or have in his possession for the purpose of so supplying, a leaflet which -

(a) falsely describes the product, or

(b) is likely to mislead as to the nature or quality of the product or as to the uses or effects of medicinal products of that description.

(4) No person shall, in the course of a business carried on by him, supply a product to which [F121the 2001 Directive applies], unless

(a) a leaflet enclosed in, or supplied with, the container or package of the product, or

(b) the container or package itself,

contains the particulars which a leaflet relating to the product is required by regulations under subsection (1) of this section to contain, and does so in the manner required by such regulations.

87. Requirements as to containers.

(1) The … Ministers may make regulations prohibiting the sale or supply of medicinal products otherwise than in containers which comply with such requirements as the Ministers consider necessary or expedient for any of the purposes specified in section 85(2) of this Act, or for the purpose of preserving the quality of the products, and in particular, may by the regulations require such containers to be of such strength, to be made of such materials, and to be of such shapes or patterns, as may be prescribed.

(2) No person shall, in the course of a business carried on by him, sell or supply, or have in his possession for the purpose of sale or supply, any medicinal product in such circumstances as to contravene any requirements imposed by regulations under this section which are applicable to that product.

88. Distinctive colours, shapes and markings of medicinal products.

(1) Regulations made by the . Ministers may impose such requirements as, for any of the purposes specified in section 85(2) of this Act, the Ministers consider necessary or expedient with respect to any one or more of the following matters, that is to say -

(a) the colour of the products;

(b) the shape of the products; and

(c) distinctive marks to be displayed on the products.

(2) Regulations made under this section may provide that medicinal products of any such description, or falling within any such class, as may be specified in the regulations shall not except in such circumstances (if any) as may be so specified, be of any such colour or shape, or display any such mark, as may be so specified.

(3) No person shall, in the course of a business carried on by him, sell or supply, or have in his possession for the purpose of sale or supply, any medicinal product which contravenes any requirements imposed by regulations under this section.

89. Display of information on automatic machines.

(1) Regulations made by the … Ministers may impose such requirements as they consider necessary or expedient with respect to the display on automatic machines of information relating to medicinal products offered or exposed for sale by means of such machines.

(2) No person shall offer or expose for sale any medicinal product by means of an automatic machine in such circumstances as to contravene any requirements imposed by regulations under this section which are applicable to that product.

90. ...

91. Offences under Part V, and supplementary provisions.

(1) Subject to sections 121 and 122 of this Act, any person who contravenes the provisions of section 85(5), section 86(3) or (4) … of this Act shall be guilty of an offence and liable -

(a) on summary conviction, to a fine not exceeding £400;

(b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.

(2) Any regulations made under this Part of this Act may provide that any person who contravenes the regulations, or who contravenes the provisions of section 85(3), section 86(2) or section 87(2) of this Act …, shall be guilty of an offence and -

(a) shall be liable on summary conviction to a fine not exceeding £400 or such lesser sum as may be specified in the regulations, and

(b) if the regulations so provide, shall be liable on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both.

(3) Without prejudice to the application of section 129(5) of this Act, any power to make regulations conferred by sections 85 to 87 of this Act may be exercised so as to impose requirements either in relation to medicinal products generally or in relation to medicinal products of a particular description, or falling within a particular class, specified in the regulations ….

(4) In this Part of this Act "requirements" includes restrictions.

Part VI

Promotion of sales of medicinal products

92. Scope of Part VI.

(1) Subject to the following provisions of this section, in this Part of this Act "advertisement" includes every form of advertising, whether in a publication, or by the display of any notice, or by means of any catalogue, price list, letter (whether circular or addressed to a particular person) or other document, or by words inscribed on any article, or by means of a photograph, film, sound recording or broadcast, or in any other way, and any reference to the issue of an advertisement shall be construed accordingly.

(2) Notwithstanding anything in the preceding subsection, in this Part of this Act "advertisement" does not include spoken words except

(a) words forming part of a sound recording or film sound track. . ., and

(b) words broadcast.

(3) Except as provided by section 95 of this Act, for the purposes of this Part of this Act neither of the following shall be taken to constitute the issue of an advertisement, that is to say -

(a) the sale or supply, or offer or exposure for sale or supply, of a medicinal product in a labelled container or package;

(b) the supply, with a medicinal product of any description, of a leaflet relating solely to medicinal products of that description.

(4) In this Part of this Act "commercially interested party", in relation to medicinal products of any description, means any person who -

(a) is the holder of a licence under Part II of this Act which is applicable to medicinal products of that description, or

(b) not being the holder of such a licence, is a person who, in the course of a business carried on by him, is engaged, in relation to medicinal products of that description, in any such activities as are mentioned in subsection (2) or subsection (3) of section 7 or in subsection (2) or subsection (3) or (3A) of section 8 of this Act, or

(c) sells by retail any medicinal products of that description in the course of a business carried on by him,

and any reference to the request or consent of a commercially interested party includes a reference to any request made or consent given by a person acting on behalf of a commercially interested party; and "relevant business" means any business which consists of or includes the sale or supply of medicinal products.

(5) In this Part of this Act "representation" means any statement or undertaking (whether constituting a condition or a warranty or not) which consists of spoken words other than words falling within paragraph (a) or paragraph (b) of subsection (2) of this section, and any reference to making a representation shall be construed accordingly.

(6) In this section "film", "sound recording", "broadcast" and related expressions, have the same meaning as in Part I of the Copyright, Designs and Patents Act 1988 (copyright).

93. False or misleading advertisements and representations.

(1) Subject to the following provisions of this section, any person who, being a commercially interested party, or at the request or with the consent of a commercially interested party, issues, or causes another person to issue, a false or misleading advertisement relating to medicinal products of any description shall be guilty of an offence.

(2) Where a licence under Part II of this Act is in force which is applicable to medicinal products of a particular description, and, in accordance with the provisions of the licence, the purposes for which medicinal products of that description may be recommended to be used are limited to those specified in the licence, then, subject to the following provisions of this section, any person who, being a commercially interested party, or at the request or with the consent of a commercially interested party, issues, or causes another person to issue, an advertisement relating to medicinal products of that description which consists of or includes unauthorised recommendations shall be guilty of an offence.

(3) Subject to the following provisions of this section, any person who in the course of a relevant business carried on by him, or while acting on behalf of a person carrying on such a business, makes a false or misleading representation relating to a medicinal product in connection with the sale, or offer for sale, of that product shall be guilty of an offence; and any person who, in the course of such a business or while acting on behalf of a person carrying on such a business, makes a false or misleading representation relating to medicinal products of a particular description -

(a) to a practitioner for the purpose of inducing him to prescribe or supply medicinal products of that description, or

(b) to a patient or client of a practitioner for the purpose of inducing him to request the practitioner to prescribe medicinal products of that description, or

(c) to a person for the purpose of inducing him to purchase medicinal products of that description from a person selling them by retail,

shall be guilty of an offence.

(4) Where in the circumstances specified in subsection (2) of this section any person, in the course of a relevant business carried on by him, or while acting on behalf of a person carrying on such a business,

(a) in connection with the sale, or offer for sale, of a medicinal product of the description in question, makes a representation relating to the product which consists of or includes unauthorised recommendations, or

(b) for any such purpose as is specified in paragraphs (a) to (c) of subsection (3) of this section makes a representation relating to medicinal products of that description which consists of or includes unauthorised recommendations,

that person, subject to the following provisions of this section, shall be guilty of an offence.

(5) Where a person is charged with an offence under this section, it shall be a defence for him to prove

(a) where the offence charged is under subsection (1) or subsection (3) of this section, that he did not know, and could not with reasonable diligence have discovered, that the advertisement or representation was false or misleading;

(b) where the offence charged is under subsection (2) or subsection (4) of this section, that he did not know, and could not with reasonable diligence have discovered, that the recommendations made by the advertisement or representation were unauthorised recommendations.

(6) Without prejudice to the last preceding subsection, where a person is charged with an offence under this section in respect of the issue of an advertisement, it shall be a defence for him to prove that he is a person whose business it is to issue or arrange for the issue of advertisements, and that either

(a) he received the advertisement for issue in the ordinary course of business and issued it, or arranged for it to be issued, either unaltered or without any alteration except in respect of lettering or lay-out, or

(b) not being a commercially interested party, he received from a commercially interested party the information on which the advertisement was based and in the ordinary course of business prepared the advertisement in accordance with that information for issue at the request of that party,

and (in either case) that he did not know and had no reason to suspect that the issue of the advertisement would amount to an offence under this section.

(7) For the purposes of this section an advertisement (whether it contains an accurate statement of the composition of medicinal products of the description in question or not) shall be taken to be false or misleading if (but only if)

(a) it falsely describes the description of medicinal products to which it relates, or

(b) it is likely to mislead as to the nature or quality of medicinal products of that description or as to their uses or effects,

and any reference in this section to a false or misleading representation shall be construed in a corresponding way.

(8) The preceding provisions of this section shall have effect subject to section 121 of this Act.

(9) Any person guilty of an offence under this section shall be liable -

(a) on summary conviction, to a fine not exceeding £400;

(b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.

(10) In this section "unauthorised recommendations", in relation to the circumstances specified in subsection (2) of this section, means recommendations whereby medicinal products of a description to which the licence in question is applicable are recommended to be used for purposes other than those specified in the licence.

94. Advertisements requiring consent of holder of product licence.

(1) Where a product licence under this Act is in force which is applicable to medicinal products of a particular description, then, except with the consent of the holder of the licence,

(a) no commercially interested party (other than the holder of the licence) shall issue, or cause another person to issue, any advertisement relating to medicinal products of that description; and

(b) no person who is not a commercially interested party shall, at the request or with the consent of a commercially interested party, issue, or cause another person to issue, any such advertisement.

(2) Subject to section 121 of this Act, any person who contravenes the preceding subsection shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 3 on the standard scale.

95. Powers to regulate advertisements and representations.

(1) The … Ministers may by regulations prohibit any one or more of the following, that is to say -

(a) the issue of advertisements relating to medicinal products of a description, or falling within a class, specified in the regulations;

(b) the issue of advertisements likely to lead to the use of any medicinal product, or any other substance or article, for the purpose of treating or preventing a disease specified in the regulations or for the purpose of diagnosis of a disease so specified or of ascertaining the existence, degree or extent of a physiological condition so specified or of permanently or temporarily preventing or otherwise interfering with the normal operation of a physiological function so specified, or for the purpose of artificially inducing a condition of body or mind so specified;

(c) the issue of advertisements likely to lead to the use of medicinal products of a particular description or falling within a particular class specified in the regulations, or the use of any other substance or article of a description or class so specified, for any such purpose as is mentioned in paragraph (b) of this subsection;

(d) the issue of advertisements relating to medicinal products and containing a word or phrase specified in the regulations, as being a word or phrase which, in the opinion of the … Ministers, is likely to mislead the public as to the nature or effects of the products or as to any condition of body or mind in connection with which the products might be used.

(2) Where any regulations are made in accordance with paragraph (b), paragraph (c) or paragraph (d) of the preceding subsection, the regulations may prohibit the making of any representation likely to lead to the use of a medicinal product or other substance or article to which the regulations apply for a purpose specified in the regulations in accordance with paragraph (b) of that subsection, or containing a word or phrase specified in the regulations in accordance with paragraph (d) of that subsection, if the representation –

(a) is made in connection with the sale or supply, or offer for sale or supply, of a medicinal product or other substance or article to which the regulations apply, or

(b) is made to a person for the purpose of inducing him to purchase such a medicinal product, substance or article from a person selling by retail medicinal products or other substances or articles to which the regulations apply, or

(c) in the case of medicinal products of a description to which the regulations apply, is made to a practitioner for the purpose of inducing him to prescribe or supply medicinal products of that description or is made to a patient or client of a practitioner for the purpose of inducing him to request the practitioner to prescribe medicinal products of that description.

(3) Without prejudice to the preceding provisions of this section, the … Ministers may by regulations impose such requirements as, for any of the purposes specified in the next following subsection, they consider necessary or expedient with respect to any one or more of the following matters, that is to say

(a) the particulars which advertisements relating to medicinal products must contain;

(b) the form of any such advertisements; and

(c) in the case of advertisements by way of cinematograph films or television, the duration for which, and the manner in which, any part of such an advertisement which contains particulars of a description specified in the regulations must be exhibited;

and any such regulations may prohibit the use, in relation to medicinal products of a description specified in the regulations, of advertisements of any particular kind so specified.

(4) The purposes referred to in subsection (3) of this section are -

(a) securing that adequate information is given with respect to medicinal products;

(b) preventing the giving of misleading information with respect to such products;

(c) promoting safety in relation to such products.

(5) Without prejudice to the application of section 129(5) of this Act, any prohibition imposed by regulations under this section may be a total prohibition or may be imposed subject to such exceptions as may be specified in the regulations.

(6) Any regulations made under this section may provide that any person who contravenes the regulations shall be guilty of an offence and

(a) shall be liable on summary conviction to a fine not exceeding £400 or such lesser sum as may be specified in the regulations, and

(b) if the regulations so provide, shall be liable on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both.

(7) Section 92(3) of this Act shall not have effect for the purposes of paragraphs (b) to (d) of subsection (1) of this section.

96. Advertisements and representations directed to practitioners.

(1) On and after the relevant date, no advertisement relating to medicinal products of a particular description, other than a data sheet, shall be sent or delivered to a practitioner -

(a) by a commercially interested party, or

(b) by any person at the request or with the consent of a commercially interested party,

unless the conditions specified in subsection (3) of this section are fulfilled.

(2) On and after the relevant date, no representation likely to promote the use of medicinal products of a particular description referred to in the representation shall be made to a practitioner by a person carrying on a relevant business, or by a person acting on behalf of a person carrying on such a business, unless the conditions specified in subsection (3) of this section are fulfilled.

(3) Those conditions are -

(a) that a data sheet relating to medicinal products of the description in question is sent or delivered to the practitioner with the advertisement, or is delivered to him at the time when the representation is made, or that such a data sheet has been sent or delivered to him not more than fifteen months before the date on which the advertisement is sent or delivered or the representation is made, and

(b) that the advertisement or representation is not inconsistent with the particulars contained in the data sheet.

(4) For the purposes of this section the relevant date -

(a) in relation to medicinal products of any description to which neither subsection (2) nor subsection (3) of section 16 of this Act is applicable, is the first appointed day, and

(b) in relation to medicinal products of any description to which either of those subsections is applicable, is the date of expiry of the period of six months from the date (or, if more than one, the latest date) on which, by virtue of one or more orders under section 17 of this Act, those subsections cease (or, if only one of them is applicable, that subsection ceases) to have effect in relation to them.

(5) Subject to section 121 of this Act, any person who contravenes subsection (1) or subsection (2) of this section shall be guilty of an offence, and, if he contravenes that subsection by not complying with the condition specified in paragraph (b) of subsection (3) of this section, shall be liable -

(a) on summary conviction, to a fine not exceeding £400, or

(b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both,

and, in any other case, shall be liable on summary conviction to a fine not exceeding level 3 on the standard scale.

(6) In this and the next following section "data sheet" means a document relating to medicinal products of a particular description, which is prepared by or on behalf of the holder of a product licence which is applicable to medicinal products of that description and which

(a) complies with such requirements as to dimensions and form, as to the particulars to be contained in it, and as to the manner (whether in respect of type, size, colour or disposition of lettering or otherwise) in which any such particulars are to be so contained, as may be prescribed for the purposes of this subsection, and

(b) does not contain any information relating to medicinal products of that description except the particulars so prescribed.

(7) Nothing in this section applies in relation to a relevant medicinal product, as defined by paragraph (1) of regulation 2 of the Medicines (Advertising) Regulations 1994, in respect of which there is required to exist a summary of product characteristics as defined by that paragraph.

97. Power for licensing authority to require copies of advertisements.

(1) The licensing authority may serve on any person a notice requiring him, within such time as may be specified in the notice, to furnish to the licensing authority such number of copies (not exceeding twelve) as may be so specified of any advertisement (including any data sheet) relating to medicinal products, or to medicinal products of a description or falling within a class so specified, which he has issued, or has caused to be issued, within the period of twelve months ending with the date of service of the notice, and which he has so issued, or caused to be issued -

(a) being a commercially interested party, or

(b) at the request or with the consent of a commercially interested party.

(2) Any person who without reasonable excuse fails to comply with any requirement imposed on him by a notice under this section shall be guilty of an offence, and shall be liable on summary conviction to a fine not exceeding level 3 on the standard scale.

Part VII

British Pharmacopoeia and other publications

98. . . .

99. New editions of British Pharmacopoeia, and other compendia.

(1) The appropriate body shall, at any such time as may be determined in accordance with subsection (5) of this section, prepare or cause to be prepared a new edition of the British Pharmacopoeia, containing such relevant information relating to substances and articles to which this subsection applies as may be so determined.

(2) The substances and articles to which the preceding subsection applies are -

(a) substances and articles (whether medicinal products or not) which are or may be used in the practice of medicine (other than veterinary medicine), surgery (other than veterinary surgery), dentistry or midwifery, and

(b) substances and articles used in the manufacture of substances or articles falling within the preceding paragraph.

(3) Without prejudice to subsection (1) of this section, the appropriate body may, at any such time as may be determined in accordance with subsection (5) of this section, prepare or cause to be prepared any such compendium or edition as is mentioned in either of the following paragraphs, that is to say -

(a) a compendium (other than the British Pharmacopoeia) containing such relevant information relating to substances and articles to which subsection (1) of this section applies, or any class of such substances and articles, as may be so determined, or, where such a compendium has been published under this section, a new edition of that compendium;

(b) a compendium containing such relevant information relating to substances and articles to which this paragraph applies, or any class of such substances and articles, as may be so determined, or, where such a compendium has been published under this section, a new edition of that compendium.

(4) The substances and articles to which subsection (3)(b) of this section applies are

(a) substances and articles (whether veterinary medicinal products or not) which are or may be used in the practice of veterinary medicine or veterinary surgery, and

(b) substances and articles used in the manufacture of substances and articles falling within the preceding paragraph.

(5) Anything falling to be determined for the purposes of subsection (1) or subsection (3) of this section

(a) except where the appropriate body is the Commission, shall be determined in accordance with directions given by the Commission, or

(b) where the appropriate body is the Commission, shall be determined by the Commission.

(6) Where the appropriate body has prepared or caused to be prepared a new edition of the British Pharmacopoeia or any such compendium or new edition of a compendium as is mentioned in subsection (3) of this section, then, on the recommendation of the Commission, the .. Ministers shall cause it to be published…:

Provided that no edition or compendium shall be published under this subsection before the vesting date.

(7) In this Part of this Act - “the appropriate body”, in relation to any work falling to be prepared under this Part of this Act, means the committee (if any) established under section 4 of this Act whose functions consist of or include the preparation of that work or, if for the time being there is no such committee, means the Commission; “relevant information”, in relation to any substances or articles, means any information consisting of descriptions of, standards for, or notes or other matter relating to, those substances or articles; “veterinary medicinal product” has the same meaning as in the Veterinary Medicines Regulations 2006.

100. Lists of names.

(1) The appropriate body shall, whenever -

(a) if the appropriate body is a committee established under section 4 of this Act, they are directed by the Commission to do so, or

(b) if that body is the Commission, the Commission consider it expedient to do so,

prepare or cause to be prepared a list of names appearing to that body to be suitable names to be used as the names of any substances and articles to which subsection (1) or subsection (3)(b) of section 99 of this Act applies and to be placed at the head of monographs relating to those substances or articles in any edition of the British Pharmacopoeia, or in any compendium or edition of a compendium, prepared under that section.

(2) Where any such list has been prepared in pursuance of the preceding subsection, then, on the recommendation of the Commission, the Ministers shall cause it to be published.

(3) A list may be prepared and published under this section in substitution for, and so as to supersede, any list previously prepared and published thereunder.

101. Other publications.

(1) The appropriate body shall, whenever -=

(a) if the appropriate body is a committee established under section 4 of this Act, they are directed by the Commission to do so, or

(b) if that body is the Commission, the Commission consider it expedient to do so,

prepare or cause to be prepared publications of any such description not falling within section 99 or section 100 of this Act as may be determined for the purposes of this subsection, being publications containing such relevant information relating to substances and articles to which subsection (1) or subsection (3)(b) of section 99 of this Act applies as may be so determined.

(2) Where the appropriate body has prepared or caused to be prepared a publication under this section, then, on the recommendation of the Commission, the … Ministers may cause it to be published and may arrange for it to be made available for sale to the public or to be otherwise distributed as the Ministers … may determine.

(3) In relation to a journal or other publication of a periodical nature a direction of the Commission under subsection (1)(a) of this section, or a recommendation of the Commission under subsection (2) of this section, may be given either

(a) in relation to a particular issue of the publication, or

(b) so as to have effect, while the direction or recommendation remains in force, in relation to each successive issue of the publication.

(4) Subsection (5) of section 99 of this Act shall have effect for the purposes of subsection (1) of this section as it has effect for the purposes of subsections (1) and (3) of that section.

102. Supplementary provisions.

(1) The provisions of subsections (1) to (6) of section 99 of this Act shall have effect in relation to the preparation and publication of amendments of -

(a) the British Pharmacopoeia (whether it is the edition of the Pharmacopoeia current immediately before the vesting date or any new edition of it published under that section), and

(b) any compendium, or new edition of a compendium, published under that section,

as those provisions have effect in relation to the preparation and publication of new editions of the British Pharmacopoeia or any such compendium, as the case may be.

(2) At any time on or after the vesting date the … Ministers may publish any amendment of the British Pharmacopoeia or of any such compendium which in the opinion of the Ministers is necessary for the purpose of giving effect to the Convention referred to in section 65(7) of this Act.

(3) The provisions of section 100 of this Act shall have effect in relation to the preparation and publication of amendments of any list published under that section as those provisions have effect in relation to the preparation and publication of any such list.

(4) Copies of -

(a) any new edition of the British Pharmacopoeia or of any compendium or new edition of a compendium published under section 99 of this Act;

(b) any list published under section 100 of this Act; and

(c) any such amendment as is mentioned in the preceding provisions of this section,

shall, in accordance with arrangements made by the … Ministers, be made available for sale to the public.

(5) Every such copy shall specify the date on which the subject-matter contained in it (whether it is a new edition of the British Pharmacopoeia, or a compendium or new edition of a compendium, or a list of names, or an amendment) is to take effect; and the … Ministers shall also give notice of that date by notices published in the Gazette not less than twenty-one days before that date.

(6) Any document purporting to be such a copy as is mentioned in subsection (4) of this section, and to be printed by a person named in the relevant notices published in the Gazette as being a person authorised by the … Ministers to print copies of the subject-matter contained in it, shall be received in evidence as being a true copy of that subject-matter and shall be evidence (and, in Scotland, shall be sufficient evidence) of the date on which that subject-matter came into operation.

(7) In this section ….. amendment" includes addition and deletion.

103. Construction of references to specified publications.

(1) In this section "specified publication" means any of the following, that is to say -

(a) the European Pharmacopoeia;

(b) the British Pharmacopoeia;

(c) the British Pharmaceutical Codex;

(ca) the International Pharmacopoeia;

(cb) the Cumulative List of Recommended International Nonproprietary Names;

(d) …;

(e) the British National Formulary;

(f) the Dental Practitioners' Formulary;

(g) any compendium prepared under subsection (3) and published under subsection (6) of section 99 of this Act; and

(h) any list of names prepared and published under section 100 of this Act.

(2) Where any licence granted or certificate issued under Part II of this Act refers to a specified publication, but not to a particular edition of that publication, then, for the purpose of determining whether anything done, at a time when the licence or certificate is in force, is done in accordance with the licence or certificate, the reference shall, unless the licence or certificate otherwise expressly provides, be construed as a reference to the current edition of that publication as in force at that time.

(3) Where under any enactment contained in this Act or in any other Act (whether passed before or after the passing of this Act) there is power to make any regulations, rules, order, list or other instrument which is to have effect by virtue of, or for the purposes of, that enactment, and an instrument made in the exercise of that power -

(a) could be made so as to refer to the current edition of a specified publication as in force at the time when the instrument is made, but

(b) could not, apart from this subsection, be made so as to refer to the current edition of a specified publication as in force at a subsequent time,

the power to make the instrument may (unless, in the case of an enactment passed after this Act, the enactment otherwise expressly provides) be exercised so as to refer to the current edition of a specified publication as in force at such time (whether before, at or after the time when the instrument is made) as may be specified in, or determined in accordance with, the instrument.

(4) Where any such power as is mentioned in subsection (3) of this section (in this subsection referred to as "the primary power") includes power to vary instruments made in the exercise of the primary power, subsection (3) of this section shall have effect in relation to any exercise of the power to vary any such instrument (whether the instrument was made before, or is made after, the passing of this Act) as it has effect in relation to any exercise of the primary power.

(5) In this section any reference to the current edition of a specified publication as in force at a particular time is a reference to the edition of that publication in force, under whatever title, at that time together with any amendments, additions and deletions made to it up to that time; and any reference to making an instrument in the exercise of a power conferred by an enactment shall be construed as including a reference to issuing or approving such an instrument.

Part VIII

Miscellaneous and supplementary provisions

104. Application of Act to certain articles and substances.

(1) The Ministers … may by order specify any description or class of articles or substances appearing to them to be articles or substances which are not medicinal products but are manufactured, sold, supplied, imported or exported for use wholly or partly for a medicinal purpose, and may by the order direct that, subject to such exceptions and modifications as may be specified in the order, such provisions of this Act or Clinical Trials Regulations as may be so specified (including provisions so specified which relate to offences or penalties) shall have effect in relation to articles or substances of that description or class as those provisions have effect in relation to medicinal products.

(2) No order shall be made under this section unless a draft of the order has been laid before Parliament and approved by a resolution of each House of Parliament.

105. Application of Act to certain other substances which are not medicinal products.

(1) The Ministers may by order specify any substance appearing to the Ministers to be a substance which is not itself a medicinal product but

(a) is used as an ingredient in the manufacture of medicinal products, or

(b) if used without proper safeguards, is capable of causing danger to the health of the community…,

and direct that, subject to such exceptions and modifications as may be specified in the order, such provisions of this Act or the Clinical Trials Regulations as may be so specified (including any provisions so specified which relate to offences or penalties) shall have effect in relation to that substance as those provisions have effect in relation to medicinal products.

(2) The power conferred by the preceding subsection may be exercised in relation to a class of substances if it appears to the Ministers that the conditions specified in paragraph (a) or paragraph (b) of that subsection are fulfilled in relation to all substances falling within that class.

(3) No order shall be made under this section -

(a) in relation to a substance as being a substance in respect of which the condition specified in subsection (1)(b) of this section is fulfilled, or

(b) in relation to a class of substances as being substances in respect of which that condition is fulfilled,

unless a draft of the order has been laid before Parliament and approved by a resolution of each House of Parliament.

106. Extension of references to carrying on business.

(1) The Ministers may by order direct that such provisions of this Act as may be specified in the order, in so far as they relate to things done by a person in the course of a business carried on by him, shall have effect, subject to such exceptions and modifications as may be specified in the order, as if in those provisions any reference to a business included a reference to an activity (other than a business) of a description specified in the order.

(2) Without prejudice to the preceding subsection, the Ministers may by order direct that such provisions of this Act as may be specified in the order, in so far as they relate to things done by a person in the course of a business carried on by him, shall have effect, subject to such exceptions and modifications as may be specified in the order, as if, in such circumstances as may be so specified, a business carried on by a person·s employer were a business carried on by that person.

107. Validity of decisions and proceedings relating thereto.

(1) Except as provided by the following provisions of this section, the validity of any decision of the licensing authority under Part II of this Act or of a Minister under section 75 of this Act, and the validity of any licence or certificate granted or issued or other thing done in pursuance of any such decision, shall not be questioned in any legal proceedings.

(2) If the person to whom such a decision relates desires to question the validity of the decision on the grounds -

(a) that it is not within the powers of this Act, or

(b) that any of the requirements of this Act or of any regulations made under this Act, which are applicable to the matter to which the decision relates, have not been complied with,

that person may, at any time within the period of three months from the date on which notice of the decision is served on him, make an application to the High Court under this section.

(3) On any application under this section the High Court –

(a) may by interim order suspend the operation of the decision to which the application relates until the final determination of the proceedings;

(b) if satisfied that the decision is not within the powers of this Act, or that the interests of the person making the application have been substantially prejudiced by a failure to comply with any of the requirements mentioned in subsection (2)(b) of this section, may quash the decision.

(4) Where a decision to grant a licence or certificate is quashed under this section, any licence or certificate granted in pursuance of that decision shall be void, and any proceedings on the application for the grant of the licence or certificate may be continued as if no such decision had been made.

(5) In the application of this section to Scotland, any reference to the High Court shall be construed as a reference to the Court of Session.

(6) In the application of this section to Northern Ireland, any reference to the High Court shall be construed as a reference to a judge of the High Court of Justice in Northern Ireland.

108. Enforcement in England and Wales.

(1) It shall be the duty of the appropriate Minister to enforce in England and Wales, or to secure the enforcement in England and Wales of, the provisions of this Act and any regulations and orders made under it.

(2) For the purpose of performing that duty in relation to -

(a) the provisions of any order made under paragraph (a) of section 62(1) of this Act and of section 63(b), sections 64 and 65, subsections (3) to (5) of section 85, and sections 87(2), 88(3) and 89(2) of this Act, in the application of any of those provisions to the retail sale, offer or exposure for retail sale, or possession for the purpose of retail sale, of medicinal products and to the supply, offer or exposure for supply, or possession for the purpose of supply, of medicinal products in circumstances corresponding to retail sale;

(b) the provisions of subsections (2) and (3) of section 86 of this Act, in their application to the supply, or possession for the purpose of supply, of leaflets with medicinal products sold or to be sold by retail, or supplied or to be supplied in circumstances corresponding to retail sale; and

(c) the provisions of sections 93 and 94 of this Act and any regulations made under section 95 of this Act,

the appropriate Minister shall, in respect of each area for which there is a drugs authority make arrangements or give directions whereby the Pharmaceutical Society, or the drugs authority for that area, or both the Society and that authority, to such extent as, in the case of that Society or authority, the arrangements or directions may provide, shall have power concurrently with the appropriate Minister, or shall be under a duty concurrently with him, to enforce the provisions specified in paragraphs (a) and (b) of this subsection, in their application as mentioned in those paragraphs, and the provisions and regulations specified in paragraph (c) of this subsection.

(3) Any arrangements made with, or directions given to, the Pharmaceutical Society under subsection (2) of this section, in so far as they relate to the provisions and regulations specified in paragraph (c) of that subsection, shall be limited to the enforcement of those provisions and regulations in respect of -

(a) any advertisement issued or representation made on or in any premises, ship, aircraft, vehicle, stall or place where medicinal products are sold by retail or are supplied in circumstances corresponding to retail sale, and

(b) any advertisement displayed on, or in close proximity to, an automatic machine in which medicinal products are offered or exposed for sale.

(4) Regulations made jointly by the Minister of Health and the Minister of Agriculture, Fisheries and Food may provide that any such body to which this subsection applies as may be specified in the regulations shall, to such extent as in the case of that body may be so specified, and either -

(a) in respect of England and Wales generally, or

(b) in respect of such area in England or Wales as may be so specified,

have power concurrently with the appropriate Minister, or be under a duty concurrently with him, to enforce any regulations made under section 66 of this Act.

(5) Subsection (4) of this section applies to the following bodies, that is to say, the Pharmaceutical Society, any drugs authority, the council of any county district which is not a drugs authority and the overseers of the Inner Temple and the Middle Temple.

(6) The Pharmaceutical Society shall be under a duty, concurrently with the appropriate Minister, -

(a) to enforce the provisions of sections .. 52 and 58 of this Act in their application to England and Wales;

(b) to enforce the provisions of any regulations made under section 60 or section 61 of this Act in their application to premises in England and Wales at which medicinal products are sold by retail or are supplied in circumstances corresponding to retail sale; and

(c) to enforce the provisions of sections 78 of this Act, and of any regulations made under section 79(2) of this Act, in their application to England and Wales.

(7) Regulations made jointly by the Minister of Health and the Minister of Agriculture, Fisheries and Food may provide that, in respect of each area in England or Wales for which there is a food and drugs authority, the Pharmaceutical Society, or the food and drugs authority for that area, or both the Society and that authority, to such extent as, in the case of that Society or authority, the regulations may provide, shall have power concurrently with the appropriate Minister, or shall be under a duty concurrently with him, to enforce the provisions of sections 53 and 54 of this Act.

(8) ….

(9) Notwithstanding anything in subsections (2) to (7) of this section, no duty or power conferred or imposed by or under any of those subsections shall be performed or be exercisable in relation to -

(a) any hospital, or

(b) so much of any premises as is used by a practitioner for carrying on his practice, or

(c) so much of any premises (not falling within either of the preceding paragraphs) as is used for veterinary medicine or veterinary surgery for the purposes of any institution.

(10) If the appropriate Minister is satisfied, after making such inquiry as he thinks fit, that the Pharmaceutical Society or any other body on whom a duty to enforce any provisions is imposed by or under subsections (4) to (6A), (7) of this section have in relation to any matter failed to perform that duty, and that the public interest requires that the provisions in question should be enforced in relation to it, he may determine that he will himself enforce those provisions in relation to that matter.

(11) In this section “the … Minister” -

(a) ….

(b) … means the Secretary of State.

(12) In this section “drugs authority” means -

(a) as respects each London borough, metropolitan district, county borough or non-metropolitan county, the council of that borough, district, county borough or county; and

(b) as respects the City of London (including the Temples), the Common Council of that City.

109. Enforcement in Scotland.

(1) It shall be the duty of the Secretary of State to enforce in Scotland, or to secure the enforcement in Scotland of, the provisions of this Act and of any regulations and orders made under it.

(2) Subsections (2) and (3) and (6) to (10) of section 108 of this Act shall have effect in relation to Scotland as if -

(a) any reference to the appropriate Minister or to the Minister of Health and the Minister of Agriculture, Fisheries and Food acting jointly were a reference to the Secretary of State;

(b) any reference to England and Wales were a reference to Scotland; and

(c) references to a food and drugs authority and to the area of any such authority were references respectively to a local authority as defined by section 26(4) of the [M21]Food and Drugs (Scotland) Act 1956 and to the area of such an authority; and

(d) ….

(2A) Subsection (12) of section 108 of this Act shall have effect in relation to Scotland as if for paragraphs (a) and (b) there were substituted the words “a council constituted under section 2 of the Local Government etc. (Scotland) Act 1994”.

(3) Regulations made by the Secretary of State may provide that, to such extent as may be specified in the regulations -

(a) the Pharmaceutical Society, in respect of Scotland generally, or in respect of such area in Scotland as may be so specified,

(b) a local authority within the meaning of section 26(4) of the Food and Drugs (Scotland) Act 1956, in respect of their area,

shall have power concurrently with the Secretary of State, or be under a duty concurrently with him, to enforce any regulations made under section 66 of this Act.

(4) Nothing in this section shall be construed as authorising an enforcement authority to institute proceedings for any offence.

110. Enforcement in Northern Ireland.

(1) Subject to the provisions of subsection (3C) of this section, it shall be the duty of the Minister of Health and Social Services for Northern Ireland (in this section referred to as ”the Minister”) to enforce in Northern Ireland, or to secure the enforcement in Northern Ireland of, the provisions of this Act and of any regulations and orders made under it.

(2) For the purpose of performing that duty in relation to the provisions specified in paragraphs (a) and (b) of subsection (2) of section 108 of this Act in their application as mentioned in those paragraphs, and the provisions and regulations specified in paragraph (c) of that subsection, within the district of any district council, the Minister may make arrangements or give directions whereby the district council, to such extent as the arrangements or directions may provide, shall have power concurrently with the Minister, or shall be under a duty concurrently with him, to enforce the provisions specified in the said paragraphs (a) and (b) in their application as so mentioned and the provisions and regulations specified in the said paragraph (c).

(3) For the purpose of performing that duty in relation to the provisions of sections 53 and 54 of this Act and any regulations made under section 66 of this Act within the district of any district council, the Minister may make arrangements or give directions whereby the district council, to such extent as the arrangements or directions may provide, shall have power concurrently with the Minister, or shall be under a duty concurrently with him, to enforce those provisions and regulations.

(3A) The Pharmaceutical Society shall be under a duty, concurrently with the Minister, to enforce the provisions of subsections (4) and (5) of section 72A of this Act in their application to Northern Ireland.

(3B) The Pharmaceutical Society shall be under a duty to enforce the other provisions of section 72A of this Act, and any regulations made under them, in their application to Northern Ireland.

(3C) The Minister shall be under no duty to enforce those other provisions, or any regulations made under them, in their application to Northern Ireland.

(3D) Notwithstanding subsection (3C) of this section the Minister is to be treated for the purposes of sections 111 to 114 of this Act—

(a) as empowered by this section to enforce those other provisions, or any regulations made under them, in their application to Northern Ireland, and

(b) to that extent as an enforcement authority in relation to those other provisions or those regulations in their application to Northern Ireland.

(4) ….

(5) Subsections (9) and (10) of section 108 of this Act shall have effect in relation to Northern Ireland as if -

(a) in the said subsection (9) the reference to subsections (2) to (7) of that section were a reference to subsections (2) and (3D) of this section; and

(b) in the said subsection (10) any reference to the appropriate Minister were a reference to the Minister within the meaning of this section, and for the words ”the Pharmaceutical Society or any other body” there were substituted the words ”any district council” and the reference to subsections (4) to (6A), (7) of that section were a reference to subsection (3) of this section.

(6) …

(7) …

(8) In this section ”district council” means a council established under the Local Government Act (Northern Ireland) 1972.

111. Rights of entry.

(1) Subject to the following provisions of this section, any person duly authorised in writing by an enforcement authority shall, on production, if required, of his credentials, have a right at any reasonable time to enter any premises -

(a) for the purpose of ascertaining whether there is or has been, on or in connection with those premises, any contravention of any provisions of this Act or of any regulations or order made under this Act which, by or under any provisions of sections 108 to 110 of this Act, that authority is required or empowered to enforce, or

(b) generally for the purposes of the performance by the authority of their functions under this Act or under any such regulations or order.

(2) Any person duly authorised in writing by an enforcement authority shall, on production, if required, of his credentials, have a right at any reasonable time -

(a) to enter any ship, aircraft or hover vehicle for the purpose of ascertaining whether there is in the ship, aircraft or vehicle any substance or article imported in contravention of any provisions of this Act or of any regulations or order made under this Act which, by or under any provisions of sections 108 to 110 of this Act, that authority is required or empowered to enforce;

(b) to enter any vehicle other than a hover vehicle, any stall or place other than premises, or any home-going ship, for any purpose for which under subsection (1) of this section the person so authorised would have a right to enter any premises.

(3) Without prejudice to subsection (1) of this section, any person duly authorised in writing by the licensing authority shall, on production, if required, of his credentials, have a right at any reasonable time to enter any premises occupied by an applicant for a licence or certificate under Part II of this Act for the purpose of verifying any statement contained in the application for the licence or certificate.

(4) Admission to any premises used only as a private dwelling-house shall not be demanded as of right by virtue of the preceding provisions of this section unless twenty-four hours' notice of the intended entry has been given to the occupier.

(5) If a justice of the peace, on sworn information in writing, is satisfied that there are reasonable grounds for entering any premises for any purpose for which a person authorised by an enforcement authority has a right to enter them in accordance with the preceding provisions of this section, and is also satisfied -

(a) that admission to the premises has been refused, or that a refusal is apprehended, and (in either case) that notice of the intention to apply for a warrant has been given to the occupier, or

(b) that an application for admission, or the giving of such a notice, would defeat the object of the entry, or

(c) that the case is one of urgency, or

(d) that the premises are unoccupied or the occupier is temporarily absent,

the justice may by warrant under his hand authorise the enforcement authority, or any person duly authorised by them, to enter the premises, if need be by force.

(6) The last preceding subsection shall have effect in relation to entering any ship, aircraft, vehicle, stall or place which may be entered under subsection (2) of this section as it has effect in relation to entering any premises, as if in the last preceding subsection any reference to the occupier were a reference to the master, commander or other person in charge of the ship, aircraft, vehicle, stall or place.

(7) Any warrant granted under this section shall continue in force for a period of one month.

(8) In this section "home-going ship" means a ship plying exclusively in inland waters or engaged exclusively in coastal voyages; and for the purposes of this subsection "inland waters" means any canal, river, lake, loch, navigation or estuary and "coastal voyage" means a voyage which starts and ends in the United Kingdom and does not involve calling at any place outside the United Kingdom.

(9) In the application of this section to Scotland, references to a justice of the peace include references to the sheriff and a magistrate.

112. Power to inspect, take samples and seize goods and documents.

(1) For the purpose of ascertaining whether there is or has been a contravention of this Act or of any regulations or order made thereunder which, by or under any provisions of sections 108 to 110 of this Act an enforcement authority is required or empowered to enforce, any person duly authorised in writing by that authority shall have a right to inspect

(a) any substance or article appearing to him to be a medicinal product;

(b) any article appearing to him to be a container or package used or intended to be used to contain any medicinal product or to be a label or leaflet used or intended to be used in connection with a medicinal product; or

(c) any plant or equipment appearing to him to be used or intended to be used in connection with the manufacture or assembly of medicinal products, and any process of manufacture or assembly of any medicinal products and the means employed, at any stage in the processes of manufacture or assembly, for testing the materials after they have been subjected to those processes.

(2) Where for the purpose specified in the preceding subsection a person authorised as mentioned in that subsection requires a sample of any substance or article appearing to him to be -

(a) a medicinal product sold or supplied or intended to be sold or supplied, or

(b) a substance or article used or intended to be used in the manufacture of a medicinal product,

he shall (if he does not obtain the sample by purchase) have a right to take a sample of that substance or article.

(3) For the purpose specified in subsection (1) of this section, any person authorised as mentioned in that subsection shall have a right

(a) to require any person carrying on a business which consists of or includes the manufacture, assembly, sale or supply of medicinal products, and any person employed in connection with such a business, to produce any books or documents relating to the business which are in his possession or under his control;

(b) to take copies of, or of any entry in, any book or document produced in pursuance of the preceding paragraph.

(4) Any person so authorised shall have a right to seize and detain any substance or article which he has reasonable cause to believe to be a substance or article in relation to which, or by means of which, an offence under this Act is being or has been committed, and any document which he has reasonable cause to believe to be a document which may be required as evidence in proceedings under this Act.

(5) For the purpose of exercising any such right as is specified in subsection (4) of this section the person having that right may, so far as is reasonably necessary in order to secure that the provisions of this Act and any regulations or order made thereunder are duly observed, require any person having authority to do so to break open any container or package or open any vending machine, or to permit him to do so.

(6) Where a person seizes any substance or article (including any document) in the exercise of such a right as is specified in subsection (4) of this section, he shall inform the person from whom it is seized, and, in the case of anything seized from a vending machine, the person whose

name and address are stated on the machine as being those of the owner of the machine, or, if no name and address are so stated, the occupier of the premises on which the machine stands or to which it is affixed.

(7) Without prejudice to the preceding provisions of this section, any person duly authorised in writing by the licensing authority shall have the rights conferred by those provisions in relation to things belonging to, or any business carried on by, an applicant for a licence or certificate under Part II of this Act, and may exercise those rights for the purpose of verifying any statement contained in the application for the licence or certificate; and, where by virtue of this subsection a person exercises any such right as is specified in subsection (4) of this section, he shall be subject to the duty imposed by subsection (6) of this section.

(8) Notwithstanding anything in the preceding provisions of this section, where a person claiming to exercise a right by virtue of this section is required to produce his credentials, the right shall not be exercisable by him except on production of those credentials.

(9) The provisions of Schedule 3 to this Act shall have effect with respect to samples obtained on behalf of enforcement authorities for the purposes of this Act.

113. Application of sampling procedure to substance or article seized under s. 112.

(1) The provisions of this section shall have effect where a person (in this section referred to as an "authorised officer") seizes a substance or article (other than a document) in the exercise of such a right as is specified in subsection (4) of section 112 of this Act (including that subsection as applied by subsection (7) of that section).

(2) If any person who in accordance with subsection (6) of that section is entitled to be informed of the seizure so requests, either at the time of the seizure or at any subsequent time, not being later than twenty-one days after he is informed of the seizure, then, subject to the next following subsection, the authorised officer shall either -

(a) set aside a sample of the substance or article seized, or

(b) treat that substance or article as a sample,

whichever he considers more appropriate having regard to the nature of that substance or article.

(3) An authorised officer shall not be required by virtue of subsection (2) of this section to set aside a sample, or to treat a substance or article as a sample, if the nature of the substance or article is such that it is not reasonably practicable to do either of those things.

(4) Where in accordance with subsection (2) of this section an authorised officer sets aside a sample, or treats a substance or article as a sample, he shall divide it into three parts, each part to be marked and sealed or fastened up in such manner as its nature will permit, and shall supply one part of it to the person who made the request under subsection (2) of this section.

(5) Paragraphs 10, 11 and 12 and paragraphs 15 to 27 of Schedule 3 to this Act shall have effect in relation to a sample set aside, or a substance or article treated as a sample, in accordance with subsection (2) of this section as they have effect in relation to a sample obtained as mentioned in paragraph 1 of that Schedule, but as if in those paragraphs

(a) any reference to a sampling officer were a reference to an authorised officer;

(b) any reference to a sample included a reference to a substance or article treated as a sample;

(c) any reference to the preceding provisions of that Schedule were a reference to the preceding provisions of this section; and

(d) any reference to the relevant enforcement authority were a reference to the authority by whom the authorised officer is authorised for the purposes of section 112 of this Act,

and as if in paragraph 24(1) of that Schedule the reference to a substance or article obtained as mentioned in paragraph 1 of that Schedule were a reference to a substance or article of which a sample has been set aside, or which has been treated as a sample, in accordance with subsection (2) of this section.

114. Supplementary provisions as to rights of entry and related rights.

(1) Any person entering any property (that is to say, any premises, ship, aircraft, vehicle, stall or place) by virtue of section 111 of this Act (whether in pursuance of a warrant or not) may take with him such other persons and such equipment as may appear to him to be necessary; and on leaving any such property which he has entered in pursuance of a warrant under that section he shall, if the property is unoccupied or the occupier (or, in the case of a ship, aircraft, vehicle, stall or place, the master, commander or other person in charge of it) is temporarily absent, leave it as effectively secured against trespass as he found it.

(2) Any person who -

(a) wilfully obstructs a person acting in pursuance of this Act and duly authorised so to act by an enforcement authority, or

(b) wilfully fails to comply with any requirement properly made to him by a person so acting under section 112 of this Act, or

(c) without reasonable cause fails to give to a person so acting any other assistance or information which that person may reasonably require of him for the purpose of the performance of his functions under this Act,

shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding level 3 on the standard scale.

(3) If any person, in giving any such information as is mentioned in subsection (2)(c) of this section, makes any statement which he knows to be false, he shall be guilty of an offence and shall be liable -

(a) on summary conviction, to a fine not exceeding £400;

(b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.

(4) Nothing in this section shall be construed as requiring a person to answer any question or give any information if to do so might incriminate that person or (where that person is married) the husband or wife of that person.

115. Analysis of samples in other cases.

(1) A person who, not being a person authorised in that behalf by an enforcement authority, has purchased a medicinal product may submit a sample of it for analysis to the public analyst for the area in which the product was purchased, or, if for the time being there is no public analyst for that area, then to the public analyst for some other area.

(2) Paragraphs 2 to 13 of Schedule 3 to this Act shall have effect in relation to a person proposing to submit a sample in pursuance of the preceding subsection, as if in those paragraphs any reference to the sampling officer were a reference to that person.

(3) Subject to the following provisions of this section, a public analyst to whom a sample is submitted under subsection (1) of this section shall as soon as practicable analyse the sample or cause it to be analysed by some other person under his direction.

(4) If the public analyst to whom a sample is submitted under subsection (1) of this section determines that for any reason an effective analysis of the sample cannot be performed by him or under his direction, he shall send it to the public analyst for some other area, and (subject to the next following subsection) that other public analyst shall as soon as practicable analyse the sample or cause it to be analysed by some other person under his direction.

(5) A public analyst to whom a sample is submitted or sent under this section may demand payment in advance of the prescribed fee, and, if he demands such payment, he shall not be required to analyse the sample or cause it to be analysed until the fee has been paid.

(6) A public analyst who has analysed a sample or caused a sample to be analysed under this section shall issue a certificate specifying the result of the analysis to the person by whom the sample was originally submitted.

(7) Any certificate issued under subsection (6) of this section shall be in a form prescribed by the Ministers and shall be signed by the public analyst who issues the certificate.

(8) Paragraphs 21 to 23 of Schedule 3 to this Act shall have effect in relation to a certificate issued under subsection (6) of this section as they have effect in relation to a certificate issued under paragraph 19 of that Schedule.

(9) Any regulations prescribing a fee for the purposes of this section shall be made by the Ministers.

(10) In this section ”public analyst” has the meaning assigned to it by paragraph 1(2) of Schedule 3 to this Act.

115A. Facilities for microbiological examinations.

A drugs authority or the council of a non-metropolitan district may provide facilities for microbiological examinations of drugs.

116. Liability to forfeiture under Customs and Excise Act 1952.

(1) For the purposes of section 49 of the Customs and Excise Management Act 1979 (forfeiture of goods improperly imported) any imported goods shall be deemed to be imported contrary to a restriction for the time being in force with respect to them under this Act if -

(a) they are goods falling within a class specified in an order made by the Ministers for the purposes of this subsection, and

(b) they are imported in such circumstances as are specified in that order.

(2) For the purposes of section 68 of the Customs and Excise Management Act 1979 (offences in relation to exportation of prohibited or restricted goods) any goods shall be deemed to be exported contrary to a restriction for the time being in force with respect to them under this Act if -

(a) they are goods falling within a class specified in an order made by the Ministers for the purposes of this subsection, and

(b) they are exported in such circumstances as are specified in that order.

(3) Any class of goods specified in an order under subsection (1) or subsection (2) of this section shall be so specified as to consist exclusively of goods appearing to the Ministers to be goods which are, or normally are, medicinal products ….

117. ….

118. Restrictions on disclosure of information.

(1) If any person discloses to any other person -

(a) any information with respect to any manufacturing process or trade secret obtained by him in premises which he has entered by virtue of section 111 of this Act, or

(b) any information obtained by or furnished to him in pursuance of this Act,

he shall, unless the disclosure was made in the performance of his duty, be guilty of an offence.

(2) Any person guilty of an offence under this section shall be liable -

(a) on summary conviction, to a fine not exceeding £400;

(b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.

119. Protection for officers of enforcement authorities.

(1) An officer of an enforcement authority shall not be personally liable in respect of any act done by him in the execution or purported execution of this Act and within the scope of his employment if he did it in the honest belief that his duty under this Act required or entitled him to do it.

(2) Where an action has been brought against an officer of an enforcement authority in respect of an act done by him in the execution or purported execution of this Act, and the circumstances are such that he is not legally entitled to require the enforcement authority to indemnify him, the authority may nevertheless indemnify him against the whole or part of the damages and costs or expenses which he may have been ordered to pay or may have incurred, if they are satisfied that he honestly believed that his duty under this Act required or entitled him to do it.

(3) In this section any reference to an officer of an enforcement authority shall be construed as including a reference to any person who, not being an officer of the authority, is authorised to act in pursuance of this Act by such an authority; and in relation to any such person any reference in this section to the scope of his employment shall be construed as a reference to the scope of the authorisation under which he acts.

120. Compensation for loss of employment or loss or diminution of emoluments.

(1) The appropriate Minister or Ministers may by regulations make provision requiring the payment by such persons as may be prescribed by or determined under the regulations, subject to such exceptions or conditions as may be so prescribed, of compensation to or in respect of persons who are, or but for any national service of theirs would be, the holders of any such situation, place or employment as may be so prescribed and who suffer loss of employment, or loss or diminution of emoluments, which is attributable to -

(a) the cessation or diminution of any work in consequence of the provisions of Part VII of this Act, or

(b) the repeal by this Act of any provision contained in the Food and Drugs Act 1955, the Food and Drugs (Scotland) Act 1956 or the Food and Drugs Act (Northern Ireland) 1958.

(2) Regulations made under this section may include provision as to the manner in which and the person to whom any claim for compensation under the regulations is to be made and for the determination of all questions arising under the regulations.

(3) Any regulations made under this section may be so framed as to have effect from a date earlier than the date on which they are made; but no regulations so framed shall place any person (other than the person required to pay the compensation) in a worse position than he would have been in if the regulations had been so framed as to have effect only as from the date on which they are made.

(4) In this section "the appropriate Minister or Ministers" means any of the following Ministers, that is to say, the [F159Secretaries of State respectively concerned with health in England and Wales and in Scotland] and the Minister of Health and Social Services for Northern Ireland, or all or any two of those Ministers acting jointly, and "national service" means any such service in any of Her Majesty's forces or other employment (whether in the service of Her Majesty or not) as may be prescribed by regulations under this section.

121. Contravention due to default of other person.

(1) Where a contravention by any person of any provision to which this section applies constitutes an offence under this Act, and is due to an act or default of another person, then, whether proceedings are taken against the first-mentioned person or not, that other person may be charged with and convicted of that offence, and shall be liable on conviction to the same punishment as might have been imposed on the first-mentioned person if he had been convicted of the offence.

(2) Where a person who is charged with an offence under this Act in respect of a contravention of a provision to which this section applies proves to the satisfaction of the court -

(a) that he exercised all due diligence to secure that the provision in question would not be contravened, and

(b) that the contravention was due to the act or default of another person,

the first-mentioned person shall, subject to the next following subsection, be acquitted of the offence.

(3) A person shall not, without the leave of the court, be entitled to rely on the defence provided by subsection (2) of this section unless, not later than seven clear days before the date of the hearing, he has served on the prosecutor a notice in writing giving such information identifying, or assisting in the identification of, the other person in question as was then in his possession.

(4) This section applies to the following provisions, that is to say, sections 63 to 65, 85 to 89, and 93 to 96, and the provisions of any regulations made under any of those sections.

122. Warranty as defence.

(1) Subject to the following provisions of this section, in any proceedings for an offence under this Act in respect of a contravention of a provision to which this section applies, it shall be a defence for the defendant to prove

(a) that he purchased the substance or article to which the contravention relates in the United Kingdom as being a substance or article which could be lawfully sold, supplied, or offered or exposed for sale, or could be lawfully sold, supplied, or offered or exposed for sale under the name or description or for the purpose under or for which he sold, supplied or offered or exposed it for sale, and with a written warranty to that effect;

(b) that at the time of the commission of the alleged offence he had no reason to believe that it was otherwise; and

(c) that the substance or article was then in the same state as when he purchased it.

(2) This section applies to the following provisions, that is to say, section 63(b), sections 64 and 65, sections 85 to 88 …and the provisions of any regulations made under any of those sections.

(3) A warranty shall not be a defence by virtue of this section unless the defendant has, not later than three clear days before the date of the hearing, sent to the prosecutor a copy of the warranty with a notice stating that he intends to rely on it and specifying the name and address of the person from whom he received it, and has also sent a like notice to that person.

(4) Where the defendant is a servant of the person who purchased the substance or article under the warranty, he shall be entitled to rely on the provisions of this section in the same way as his employer would have been entitled to do if he had been the defendant.

(5) The person by whom the warranty is alleged to have been given shall be entitled to appear at the hearing and to give evidence, and the court may, if it thinks fit, adjourn the hearing to enable him to do so.

(6) For the purposes of this section a name or description entered in an invoice shall be deemed to be a written warranty that the article or substance to which the name or description applies can be sold, supplied, or offered or exposed for sale under that name or description by any person without contravening any provision to which this section applies.

(7) In the application of this and the next following section to Scotland, any reference to the defendant shall be construed as a reference to the accused.

123. Offences in relation to warranties and certificates of analysis.

(1) If a defendant in any such proceedings as are mentioned in section 122(1) of this Act wilfully applies to any substance or article -

(a) a warranty given in relation to a different substance or article, or

(b) a certificate issued under section 115 of this Act, or under paragraph 19 of Schedule 3 to this Act, which relates to a sample of a different substance or article,

he shall be guilty of an offence.

(2) A person who, in respect of any substance or article sold by him in respect of which a warranty might be pleaded under section 122 of this Act, gives to the purchaser a false warranty in writing shall be guilty of an offence, unless he proves that when he gave the warranty he had reason to believe that the statement or description contained in it was accurate.

(3) Where the defendant in any such proceedings as are mentioned in section 122(1) of this Act relies successfully on a warranty given to him or to his employer, any proceedings for an offence under subsection (2) of this section in respect of the warranty may, at the option of the prosecutor, be taken either before a court having jurisdiction in the place where a sample of the substance or article to which the warranty relates was procured, or before a court having jurisdiction in the place where the warranty was given.

(4) Any person guilty of an offence under this section shall be liable -

(a) on summary conviction, to a fine not exceeding £400;

(b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.

124. Offences by bodies corporate.

(1) Where an offence under this Act which is committed by a body corporate is proved to have been committed with the consent and connivance of, or to be attributable to any neglect on the part of, any director, manager, secretary or other similar officer of the body corporate, or any person who was purporting to act in any such capacity, he as well as the body corporate shall be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

(2) In relation to a body corporate carrying on a retail pharmacy business as mentioned in subsection (1) of section 71 of this Act, the preceding subsection shall have effect in relation to a person who (not being such an officer of the body corporate as is mentioned in the preceding subsection)

(a) is the superintendent referred to in subsection (1) of that section, or

(b) at any premises where the business is carried on, is the pharmacist referred to in subsection (1)(a) of that section who acts under the directions of the superintendent,

as if he were such an officer of the body corporate as is mentioned in the preceding subsection.

(3) In this section ”director”, in relation to a body corporate established by or under any enactment for the purpose of carrying on under national ownership any industry or part of an industry or undertaking, being a body corporate whose affairs are managed by its members, means a member of that body corporate.

125. Prosecutions.

(1) Notwithstanding anything in section 127(1) of the Magistrates' Courts Act 1980], a magistrates' court in England or Wales may try an information for an offence under this Act if the information was laid at any time within twelve months from the commission of the offence.

(2) Notwithstanding anything in section 331 of the Criminal Procedure (Scotland) Act 1975 (limitation of time for proceedings in statutory offences) summary proceedings in Scotland for an offence under this Act may be commenced at any time within twelve months from the time when the offence was committed, and subsection 3 of the said section 331 shall apply for the purposes of this subsection as it applies for the purposes of that section.

(3) Notwithstanding anything in section 34 of the Magistrates' Courts Act (Northern Ireland) 1964, Article 19(1) of the Magistrates' Courts (Northern Ireland) Order 1981, a magistrates' court in Northern Ireland may hear and determine a complaint for an offence punishable under this Act upon summary conviction other than an offence which is also triable upon indictment if the complaint was made at any time within twelve months from the commission of the offence.

(4) Neither the Pharmaceutical Society nor any other body referred to in subsection (2) … of section 108 of this Act shall institute proceedings for an offence under this Act in respect of a contravention of a provision which, by virtue …that subsection, that Society or body have a power or duty to enforce, unless they have given to the appropriate Minister not less than twenty-eight days' notice of their intention to institute proceedings, together with a summary of the facts upon which the charges are founded.

(5) For the purposes of subsection (4) of this section the appropriate Minister, in relation to a contravention of any provision, is the Minister who in accordance with section 108 of this Act has a concurrent duty to enforce that provision.

(6) A district council (as defined by section 110 of this Act) shall not prosecute for an offence under this Act in respect of a contravention of any provision which, by virtue of subsection (2) of that section, the authority have a power or duty to enforce, unless the authority have given to the Minister of Health and Social Services for Northern Ireland not less than twenty-eight days' notice of their intention to begin the prosecution, together with a summary of the facts upon which the charges are founded.

(7) A certificate of the Minister who is the appropriate Minister for the purposes of subsection (4) of this section that the requirements of that subsection have been complied with in relation to any proceedings, and a certificate of the Minister of Health and Social Services for Northern Ireland that the requirements of subsection (6) of this section have been complied with in relation to any prosecution, shall be conclusive evidence that those requirements have been so complied with; and any document purporting to be such a certificate and to be signed by or on behalf of that Minister shall be presumed to be such a certificate unless the contrary is proved.

126. Presumptions.

(1) For the purposes of any proceedings under this Act for an offence consisting of -

(a) …

(b) offering a medicinal product for sale by retail in contravention of section 52 or section 53 of this Act, or

(c) offering a medicinal product for sale in contravention of section 63(b) of this Act,

where it is proved that the … medicinal product in question was found on a vehicle from which … medicinal products are sold, it shall be presumed, unless the contrary is proved, that the person in charge of the vehicle offered that … medicinal product for sale and, in a case falling within paragraph (b) of this subsection, that he offered it for sale by retail.

(2) For the purposes of any proceedings under this Act for an offence consisting of a contravention of so much of any provision to which this subsection applies as relates to a person's having any medicinal product … in his possession for the purpose of sale or supply, where it is proved that the medicinal product … in question was found on premises at which the person charged with the offence carries on a business consisting of or including the sale or supply of medicinal products … in which medicinal products have been incorporated, it shall be presumed, unless the contrary is proved, that he had that medicinal product … in his possession for the purpose of sale or supply.

(3) Subsection (2) of this section applies to the following provisions of this Act, that is to say, section 63(b), subsections (3) and (5) of section 85, subsection (2) of section 87 and subsection (3) of section 88….

(4) For the purposes of any proceedings under this Act for an offence consisting of a contravention of subsection (2) or subsection (3) of section 86 of this Act…, where it is proved that the leaflet in question was found on premises at which the person charged with the offence carries on a business consisting of or including the sale or supply of medicinal products …, it shall be presumed, unless the contrary is proved, that he had the leaflet in his possession for the purpose of supplying it with a medicinal product….

127. Service of documents.

Any notice or other document required or authorised by any provision of this Act to be served on any person, or to be given or sent to any person, may be served, given or sent

(a) by delivering it to him; or

(b) by sending it by post to him at his usual or last-known residence or place of business in the United Kingdom; or

(c) in the case of a body corporate, by delivering it to the secretary or clerk of the body corporate at its registered or principal office or sending it by post to the secretary or clerk of that body corporate at that office.

128. Financial provisions.

(1) Any expenses incurred in consequence of this Act by any of the Ministers specified in paragraphs (a) and (b) of section 1(1) of this Act, other than expenses so incurred exclusively in respect of executing this Act in Northern Ireland, shall be defrayed out of moneys provided by Parliament.

(2) There shall be defrayed out of moneys provided by Parliament any increase attributable to the provisions of this Act in -

(a) the sums payable out of moneys so provided in respect of rate support grants to local authorities in England and Wales which may arise from the inclusion, in the expenditure relevant to the fixing of the aggregate amount of those grants, of expenditure under this Act, or

(b) the sums payable out of moneys so provided under any enactment relating to local government in Scotland.

(3) . . .

(4) Where the Pharmaceutical Society or any other body enforces any provision of this Act or of any regulations or order made thereunder in the performance of a duty imposed, or the exercise of a power conferred, under section 108(2) or section 110(2) of this Act, the Minister who has a concurrent duty to enforce that provision shall pay to the Society or other body such charges as they may reasonably require to be paid in respect of expenses incurred by them in the enforcement of that provision.

(5) Where under subsection (10) of section 108 of this Act (or under that subsection as modified in relation to Northern Ireland by section 110(5) of this Act) a Minister makes a determination in respect of the enforcement of any provision in relation to a particular matter, he shall be entitled to recover from the Pharmaceutical Society or other body who were under a duty to enforce that provision in relation to that matter any expenses reasonably incurred by that Minister in taking steps to enforce that provision in relation to that matter.

(6) Any fees and other sums received by virtue of this Act by any of the Ministers specified in paragraphs (a) and (b) of section 1(1) of this Act, other than Ministers in the Government of Northern Ireland, shall be paid into the Exchequer.

(7) Such sums paid out of the Exchequer of the United Kingdom in connection with the execution of this Act as may be determined by the Joint Exchequer Board to be properly payable by the Government of Northern Ireland shall be made good by means of deductions from the Northern Ireland residuary share of reserved taxes.

129. Orders and regulations.

(1) The Ministers may make regulations for any purpose for which regulations are authorised or required to be made under this Act, other than any purpose for which any provision of this Act authorises or requires regulations to be made otherwise than by the Ministers.

(2) Any power to make orders or regulations under this Act (other than any order made by a court or judge or any order or regulations made in relation to Northern Ireland under paragraph 1.. or paragraph 6 of Schedule 4 to this Act or any regulations made solely by the Minister of Health and Social Services for Northern Ireland under section 120 of this Act) shall be exercisable by statutory instrument.

(3) Any statutory instrument consisting of –

(a) an order made under any of the following provisions of this Act, that is to say, sections 13, 15(1), .. 49, 54(2), 55(2), 56, 57(1), 58, 62, 79, 106, 116, … and 130(5)(c) and paragraph 27 of Schedule 3, or

(b) an order made under section 105 of this Act otherwise than as mentioned in subsection (3) of that section, or

(c) any regulations made under any provision, other than section 79, of this Act,

shall be subject to annulment in pursuance of a resolution of either House of Parliament.

(4) Any power to make an order under any provision, other than sections 16(1), 17, 25(1), 37(3), 52 and 69(3), of this Act shall include power to revoke or vary the order by a subsequent order made under that provision.

(5) Any power to make regulations under this Act may be exercised so as to make different provision for different areas or in relation to different cases or different circumstances to which the power is applicable, and to make any such provision subject to such exceptions, limitations and conditions (if any) as the authority making the regulations considers necessary or expedient.

(6) Before making any regulations under this Act and before making any order under this Act (except an order made in accordance with any provision of this Act under which, in case of urgency, an order can be made with immediate effect) the Ministers proposing to make the regulations or order shall consult such organisations as appear to them to be representative of interests likely to be substantially affected by the regulations or order.

(6A) ….

(7) Without prejudice to subsection (6) of this section, where any Ministers propose to make any regulations or order under Part III, Part V or Part VI of this Act, or under section 104 or section 105 of this Act, and they consult a committee established under section 4 of this Act, or the

Commission, with respect to that proposal, they shall take the advice of the committee or of the Commission into account before proceeding with those proposals.

130. Meaning of "medicinal product" and related expressions.

(1) Subject to the following provisions of this section, in this Act "medicinal product" means any substance or article (not being an instrument, apparatus or appliance) which is manufactured, sold, supplied, imported or exported for use wholly or mainly in either or both of the following ways, that is to say –

(a) use by being administered to one or more human beings … for a medicinal purpose;

(b) use, in circumstances to which this paragraph applies, as an ingredient in the preparation of a substance or article which is to be administered to one or more human beings … for a medicinal purpose.

(2) In this Act "a medicinal purpose" means any one or more of the following purposes, that is to say -

(a) treating or preventing disease;

(b) diagnosing disease or ascertaining the existence, degree or extent of a physiological condition;

(c) contraception;

(d) inducing anaesthesia;

(e) otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating, reducing or postponing, or increasing or accelerating, the operation of that function or in any other way.

(3) In paragraph (b) of subsection (1) of this section the reference to use in circumstances to which that paragraph applies is a reference to any one or more of the following, that is to say

(a) use in a pharmacy or in a hospital;

(b) use by a practitioner;

(c) use in the course of a business which consists of or includes the retail sale, or the supply in circumstances corresponding to retail sale, of herbal remedies.

(3A) …

(3B) ….

(3C) …..

(4) Notwithstanding anything in subsection (1) … of this section, in this Act "medicinal product" does not include any substance or article which is manufactured for use wholly or mainly by being administered to one or more human beings …, where it is to be administered to them –

(a) in the course of the business of the person who has manufactured it (in this subsection referred to as "the manufacturer"), or on behalf of the manufacturer in the course of the business of a laboratory or research establishment carried on by another person, and

(b) solely by way of a test for ascertaining what effects it has when so administered, and

(c) in circumstances where the manufacturer has no knowledge of any evidence that those effects are likely to be beneficial to those human beings…,

and which (having been so manufactured) is not sold, supplied or exported for use wholly or mainly in any way not fulfilling all the conditions specified in paragraphs (a) to (c) of this subsection.

(5) In this Act "medicinal product" shall also be taken not to include –

(a) substances used in dental surgery for filling dental cavities;

(b) bandages and other surgical dressings, except medicated dressings within subsection (5A) below;

(c) substances and articles of such other descriptions or classes as may be specified by an order made by the Ministers… for the purposes of this subsection.

(5A) Medicated dressings are within this subsection (and accordingly are not excluded from the definition of "medicinal product" by subsection (5)(b) above) if -

(a) their medication has a curative function which is not limited to sterilising the dressing; and

(b) they are not dressings of a kind to which the requirements of Article 2 of Council Directive 93/42/EEC (placing medical devices on the market and putting them into service) apply or would apply but for Article 4 (devices intended for special purposes) or 22 (transitional provisions) of that Directive.

(6) Where in accordance with the preceding provisions of this section a substance or article is a medicinal product immediately after it has been manufactured, imported or exported as mentioned in subsection (1) … of this section, or immediately after the first occasion on which it has been sold or supplied as mentioned in that subsection, then . . . it shall not cease to be a medicinal product for the purposes of this Act by reason only that, at any subsequent time, it is sold, supplied, imported or exported for use wholly or mainly in a way other than those specified in that subsection.

(7) …

(8) For the purposes of this Act medicinal products are of the same description if (but only if) –

(a) they are manufactured to the same specification, and

(b) they are, or are to be, sold, supplied, imported or exported in the same pharmaceutical form,

and in this Act "description", in relation to medicinal products, shall be construed accordingly.

(9) In this Act ”administer” means administer to a human being .., whether orally, by injection or by introduction into the body in any other way, or by external application, whether by direct contact with the body or not; and any reference in this Act to administering … a substance or article is a reference to administering … it either in its existing state or after it has been dissolved or dispersed in, or diluted or mixed with, some other substance used as a vehicle.

(10) For the purposes of this Act a document, advertisement or representation shall be taken to be likely to mislead as to the uses or effects of medicinal products of a particular description if it is likely to mislead as to any of the following matters, that is to say -

(a) any purposes for which medicinal products of that description can with reasonable safety be used;

(b) any purposes for which such products cannot be so used; and

(c) any effects which such products when used, or when used in any particular way referred to in the document, advertisement or representation, produce or are intended to produce.

131. Meaning of ”wholesale dealing”, ”retail sale” and related expressions.

(1) In this Act any reference to selling anything by way of wholesale dealing is a reference to selling it to a person as being a person who buys it for one or more of the purposes specified in subsection (2) of this section, except that it does not include any such sale by the person who manufactured it.

(2) The purposes referred to in the preceding subsection, in relation to a person to whom anything is sold, are the purposes of -

(a) selling or supplying it, or

(b) administering it or causing it to be administered to one or more human beings,

in the course of a business carried on by that person.

(3) In this Act any reference to selling by retail, or to retail sale, is a reference to selling a substance or article to a person as being a person who buys it otherwise than for a purpose specified in subsection (2) of this section.

(4) In this Act any reference to supplying anything in circumstances corresponding to retail sale is a reference to supplying it, otherwise than by way of sale, to a person as being a person who receives if for a purpose other than that of

(a) selling or supplying it, or

(b) administering it or causing it to be administered to one or more human beings,

in the course of a business carried on by that person.

(5) For the purposes of this section the provision of services by or on behalf of the Minister of Health, the Secretary of State or the Ministry of Health and Social Services for Northern Ireland under the National Health Service Act 1977, the National Health Service (Scotland) Act 1978 or the Health and Personal Social Services (Northern Ireland) Order 1972 shall be treated as the carrying on of a business by that Minister, the Secretary of State or that Ministry, as the case may be.

132. General interpretation provisions.

(1) In this Act, except in so far as the context otherwise requires, the following expressions have the meanings hereby assigned to them respectively, that is to say:

“Advisory Body” has the meaning given to it by paragraph 1 of Schedule 1A to this Act ;

”analysis” includes micro-biological assay but no other form of biological assay, and ”analyse” has a corresponding meaning;

…

”the appropriate committee” has the meaning assigned to it by section 4(6) of this Act;

..

”assemble”, in relation to a medicinal product, means enclosing the product (with or without other medicinal products of the same description) in a container which is labelled before the product is sold or supplied, or, where the product (with or without other medicinal products of the same description) is already enclosed in the container in which it is to be sold or supplied, labelling the container before the product is sold or supplied in it, and ”assembly” has a corresponding meaning;

”business” includes a professional practice and includes any activity carried on by a body of persons, whether corporate or unincorporate;

…

“the Clinical Trials Regulations” means the Medicines for Human Use (Clinical Trials) Regulations 2004;

”the Commission” means the Commission for Human Medicines established under this Act;

”composition”, in relation to a medicinal product, means the ingredients of which it consists and the proportions, and the degrees of strength, quality and purity, in which those ingredients are contained in it respectively;

”container”, in relation to a medicinal product, means the bottle, jar, box, packet or other receptacle which contains or is to contain it, not being a capsule, cachet or other article in which the product is or is to be administered, and where any such receptacle is or is to be contained in another such receptacle, includes the former but does not include the latter receptacle;

”contravention” includes failure to comply and ”contravene” has a corresponding meaning;

”dentist” means a person registered in the dentists register under the Dentists Act 1984 …;

…

”the 2001 Directive” means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use as amended;

”disease” includes any injury, ailment or adverse condition, whether of body or mind;

”doctor” means a registered medical practitioner person within the meaning of Schedule 1 to the Interpretation Act 1978;

”drugs authority” has the meaning assigned to it by section 108(12) of this Act;

”enforcement authority” means any Minister or body on whom a duty or power to enforce any provisions of this Act or of any regulations or order made thereunder is imposed or conferred by or under sections 108 to 110 of this Act;

“Expert Advisory Group” means an Expert Advisory Group established under paragraph 3 or 4 of Schedule 1A to this Act;

”export” means export from the United Kingdom, whether by land, sea or air, and ”import” has a corresponding meaning;

”the first appointed day” has the meaning assigned to it by section 16(1) of this Act;

”food and drugs authority” has the meaning assigned to it for the purposes of the Food and Drugs Act 1955 by section 198 of the Local Government Act 1972;

”the Gazette” means the London, Edinburgh and Belfast Gazettes;

”health centre” means a health centre maintained under section 2 or 3 of the National Health Service Act 1977 section 36 of the National Health Service (Scotland) Act 1978 or Article 5 of the Health and Personal Social Services (Northern Ireland) Order 1972;

”herbal remedy” means a medicinal product consisting of a substance produced by subjecting a plant or plants to drying, crushing or any other process, or of a mixture whose sole ingredients are two or more substances so produced, or of a mixture whose sole ingredients are one or more substances so produced and water or some other inert substance;

…

” the Homoeopathic Regulations” means the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994;

”hospital” includes a clinic, nursing home or similar institution;

”hover vehicle” means a vehicle designed to be supported on a cushion of air;

”ingredient”, in relation to the manufacture or preparation of a substance, includes anything which is the sole active ingredient of that substance as manufactured or prepared;

”labelling”, in relation to a container or package of medicinal products, means affixing to or otherwise displaying on it a notice describing or otherwise relating to the contents, and ‹label” has a corresponding meaning;

”leaflet” includes any written information;

”the licensing authority” has the meaning assigned to it by section 6 of this Act;

”licence of right” has the meaning assigned to it by section 25(4) of this Act;

”manufacture”, in relation to a medicinal product, includes any process carried out in the course of making the product, but does not include dissolving or dispersing the product in, or diluting or mixing it with, some other substance used as a vehicle for the purpose of administering it …;

“the Marketing Authorisation Regulations” means the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994;

“the Ministers” shall be construed in accordance with section 1(1) of this Act;

…

”offence under this Act” includes an offence under any regulations or order made under this Act;

”package”, in relation to any medicinal products, means any box, packet or other article in which one or more containers of the products are or are to be enclosed, and, where any such box, packet or other article is or is to be itself enclosed in one or more other boxes, packets or other articles, includes each of the boxes, packets or articles in question;

”Pharmaceutical Society” in relation to Great Britain means the General Pharmaceutical Council, and in relation to Northern Ireland means the Pharmaceutical Society of Northern Ireland;

”pharmacist” in relation to Great Britain means a person registered as a pharmacist in the register maintained under article 19 of the Pharmacy Order 2010, and in relation to Northern Ireland (subject to any order made under paragraph 1 of Schedule 4 to this Act) means a person registered in the register of pharmaceutical chemists for Northern Ireland made out and maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976;

”plant” includes any part of a plant;

…

”practitioner” (except where that word occurs as part of the expression ”veterinary practitioner”) means a doctor, dentist, veterinary surgeon or veterinary practitioner;

”prescribed” means prescribed by regulations under this Act;

”product licence”, ”manufacturer‹s licence” and ”wholesale dealer‹s licence” have the meanings assigned to them by sections 7 and 8 of this Act;

”registered pharmacy” has the meaning assigned to it by section 74 of this Act;

”retail pharmacy business” means a business (not being a professional practice carried on by a practitioner) which consists of or includes the retail sale of medicinal products other than medicinal products on a general sale list (whether medicinal products on such a list are sold in the course of that business or not);

”substance” means any natural or artificial substance, whether in solid or liquid form or in the form of a gas or vapour;

”the time allowed”, in Part II of, and Schedule 2 to, this Act has the meaning assigned to it by section 21(12) of this Act;

”treatment”, in relation to disease, includes anything done or provided for alleviating the effects of the disease, whether it is done or provided by way of cure or not;

…

”veterinary practitioner” means a person registered in the supplementary veterinary register kept under section 8 of the Veterinary Surgeons Act 1966;

”veterinary surgeon” means a person registered in the register of veterinary surgeons kept under section 2 of the Veterinary Surgeons Act 1966;

”writing” includes any form of notation, whether by hand or by printing, typewriting or any similar process, and ”written” has a corresponding meaning.

(2) For the purposes of this Act considerations of safety, in relation to any substance or article, shall be taken to include consideration of the extent (if any) to which the substance or article –

(a) if used without proper safeguards, is capable of causing danger to the health of the community, …or

(b) …

(c) may interfere with the treatment, prevention or diagnosis of disease, or

(d) may be harmful to the person administering it or (in the case of an instrument, apparatus or appliance) the person operating it,

and any reference in this Act to safety or to the interests of safety shall be construed accordingly.

(3) In this Act any reference to doing anything in accordance with a licence under Part II of this Act shall be construed as a reference to doing it in pursuance of such a licence and in compliance with any conditions and any limitations (whether as to area or otherwise) to which the licence is subject, and so as not to fall within any exceptions to which it is subject….

(4) Any reference in this Act to the holder of a licence or certificate shall be construed as a reference to the holder of a licence or certificate which is for the time being in force.

(5) For the purposes of this Act medicinal products of any description shall be taken to be effectively on the market in the United Kingdom at a particular time if (but only if) during the whole of the period of one month ending with that time adequate stocks of medicinal products of that description were available, or could within a reasonable time be made available, for sale or supply to such persons in the United Kingdom as were likely to require them.

(6) Except in so far as the context otherwise requires, any reference in this Act to an enactment shall be construed as a reference to that enactment as amended or extended by or under any other enactment, including this Act.

133. General provisions as to operation of Act.

(1) The provisions of this Act, and of any regulations or orders made under it, shall operate cumulatively; and any exemption or exception from any of those provisions shall not be construed as conferring any exemption or exception in relation to any other of those provisions.

(2) Except in so far as this Act otherwise expressly provides, and subject to the provisions of section 33 of the Interpretation Act 1889 (which relates to offences under two or more laws), the provisions of this Act shall not be construed as -

(a) conferring a right of action in any civil proceedings (other than proceedings for the recovery of a fine) in respect of any contravention of this Act or of any regulations or order made under this Act, or

(b) affecting any restriction imposed by or under any other enactment, whether contained in a public general Act or in a local or private Act, or

(c) derogating from any right of action or other remedy (whether civil or criminal) in proceedings instituted otherwise than under this Act.

(3) No exemption conferred by or under any provision of this Act shall be construed as derogating from any exemption or immunity of the Crown.

134. Special provisions as to Northern Ireland.

(1) Nothing in this Act shall authorise any department of the Government of Northern Ireland to incur any expenses attributable to the provisions of this Act, which are not expenses falling to be defrayed in accordance with section 128(1) of this Act, until provision has been made by the Parliament of Northern Ireland for those expenses to be defrayed out of moneys provided by that Parliament.

(2) …

(3) The provisions of Schedule 4 to this Act shall have effect with respect to the application of this Act in relation to Northern Ireland.

(4) In this Act ”enactment” includes an enactment of the Parliament of Northern Ireland; and (without prejudice to section 132(6) of this Act) any reference in this Act to such an enactment shall include a reference to any enactment re-enacting it with or without modifications.

(5) Sections 16(1) and 17(2)(a) of the Interpretation Act 1978] shall have the like operation in relation to any repeal by this Act of an enactment of the Parliament of Northern Ireland as it has in relation to the repeal of an enactment of the Parliament of the United Kingdom.

135. Minor and consequential amendments and repeals.

(1) The enactments of the Parliament of the United Kingdom which are specified in Schedule 5 to this Act shall have effect subject to the amendments set out in that Schedule, being minor amendments and amendments consequential upon the preceding provisions of this Act.

(2) The enactments of that Parliament which are specified in Schedule 6 to this Act are hereby repealed to the extent specified in the third column of that Schedule:

Provided that the repeal of section 47 of the Medical Act 1956 shall not take effect before the vesting date (as defined by section 98 of this Act).

(3) The enactments of the Parliament of Northern Ireland which are specified in Schedule 7 to this Act shall have effect subject to the amendments specified in that Schedule, being minor amendments and amendments consequential upon the preceding provisions of this Act.

(4) The enactments of the Parliament of Northern Ireland specified in Schedule 8 to this Act are hereby repealed to the extent specified in the third column of that Schedule.

136. Short title, extent and commencement.

(1) This Act may be cited as the Medicines Act 1968.

(2) Except as provided by section 78(5B), this Act extends to Northern Ireland.

(3) The following provisions of this Act, that is to say, sections 63 to 65, 77, 85(5), 86(3), 90(2), 93, 97 and 135, shall not come into operation on the passing of this Act but shall come into operation on such day as the Ministers may by order appoint, and different days may be so appointed for, or for different purposes of, any one or more of those provisions (including, in the case of section 135 of this Act, the amendment or repeal of different enactments to which that section is applicable).

(4) Any order made under this section may make such transitional provision as appears to the Ministers to be necessary or expedient in connection with the provisions of this Act which are thereby brought (wholly or in part) into force, including such adaptations of those provisions or any provision of this Act then in force as appear to them to be necessary or expedient in consequence of the partial operation of this Act (whether before, on or after the day appointed by the order).

SCHEDULES

SCHEDULE 1

Section 5.

Provisions Relating to Medicines Commission and Committees

1. The Ministers may make provision by regulations with respect to any one or more of the following matters, that is to say –

(a) the terms on which members of the Commission or of committees established under section 4 of this Act shall hold and vacate office, including the terms on which any person appointed as chairman of the Commission or of such a committee shall hold and vacate office as chairman;

(b) the appointment by the Commission of one or more committees consisting wholly or partly of members of the Commission, and the appointment by the Commission of a chairman in respect of each committee so appointed;

(c) the appointment by any committee established under section 4 of this Act, or the appointment jointly by two or more such committees, of one or more sub-committees consisting wholly or partly of members of that committee or those committees, as the case may be, and the appointment by that committee or by those committees, as the case may require, of a chairman in respect of each sub-committee so appointed;

(d) the terms on which members of any such sub-committee shall hold and vacate office, including the terms on which any person appointed as chairman of such a sub-committee shall hold and vacate office as chairman.

2. The Ministers shall provide the Commission and each committee established under section 4 or appointed under section 60 of this Act with such staff and such accommodation, services and other facilities as appear to the Ministers to be necessary or expedient for the proper performance of their functions.

3. The validity of any proceedings of the Commission or of any such committee or sub-committee as is mentioned in any of the preceding paragraphs shall not be affected by a vacancy among the members of the Commission, committee or sub-committee or of any defect in the appointment of any member of the Commission, committee or sub-committee.

4. The Commission and any such committee or sub-committee shall have power to regulate their procedure, including power to determine the quorum at their meetings.

5. The Ministers may pay to the members of the Commission and of any such committee or sub-committee such remuneration (if any) and such allowances as may be determined by the Ministers with the consent of the Treasury.

6. The Ministers shall defray any expenses incurred with their approval by the Commission or by any such committee or subcommittee as is mentioned in any of the preceding paragraphs.

7. Neither the Commission nor any such committee or sub-committee shall be taken to be the servant or agent of the Crown or to enjoy any status or immunity of the Crown.

SCHEDULE 1A

Section 5.

Provisions Relating to Commission on Human Medicine and Committees

1. to be found

2.

3.

4.

5.

6. (1)

(2) Regulations made under sub-paragraph (1) may include such incidental, supplemental, consequential or transitional provision as appears to the Ministers to be expedient.

SCHEDULE 2

Section 29.

Suspension, Revocation or Variation of Licence

Procedure on consultation with appropriate committee

1. Subject to paragraph 8 below, where the licensing authority propose, in the exercise of their powers under section 28 of this Act –

(a) to suspend, revoke or vary a product licence on the grounds specified in paragraph (a) or paragraph (c) of subsection (3) of that section, in a case where it appears to the licensing authority that the matters or characteristics in question are such as to affect the safety, efficacy or quality of medicinal products to which the licence relates, or

(b) to suspend, revoke or vary a product licence on any of the grounds specified in paragraph (g) or paragraph (h) of that subsection,

the licensing authority shall not suspend, revoke or vary the licence except after consultation with the appropriate committee.

2. (1) Where the appropriate committee are consulted under the preceding paragraph and are of the provisional opinion that, on such grounds as are mentioned in that paragraph, they may have to advise the licensing authority that the product licence ought to be revoked, varied or suspended, the appropriate committee shall notify the holder of the licence accordingly.

(2) A person who has been so notified may, within the time allowed, give notice of his wish to make written or oral representations to the appropriate committee.

(3) The appropriate committee shall give the holder of the licence an opportunity to make such representations in accordance with sub-paragraphs (4) to (7) of this paragraph.

(4) Subject to sub-paragraph (5) of this paragraph, the holder of the licence shall provide the appropriate committee with –

(a) his written representations or a written summary of the oral representations he intends to make; and

(b) any documents on which he wishes to rely in support of those representations,

before the end of the period of six months beginning with the date of the notice referred to in sub-paragraph (2) of this paragraph, or within such shorter period as the appropriate committee may specify in the notification under sub-paragraph (1) of this paragraph.

(5) If the holder of the licence so requests, the appropriate committee may extend the time limit referred to in sub-paragraph (4) of this paragraph, up to a maximum period of twelve months beginning with the date of the notice referred to in sub-paragraph (2) of this paragraph.

(6) The holder of the licence may not submit any additional written representations or documents once the time limit referred to in sub-paragraphs (4) and (5) of this paragraph has expired, except with the permission of the appropriate committee.

(7) If the holder gave notice of his wish to make oral representations, the appropriate committee shall, after receiving a written summary and any other documents in accordance with sub-paragraph (4) of this paragraph, arrange for the holder to make such representations at a hearing before the committee.

(8) The appropriate committee shall –

(a) take into account such representations as are made in accordance with this paragraph; and

(b) report their findings and advice to the licensing authority, together with the reasons for their advice.

3. (1) After receiving the report of the appropriate committee the licensing authority shall –

(a) decide whether to continue with the proposal to revoke, vary or suspend the product licence; and

(b) take the report into account when making their decision.

(2) The licensing authority shall then notify the holder of the licence of –

(a) the decision made pursuant to sub-paragraph (1) of this paragraph; and

(b) the advice given to them by the appropriate committee and the reasons for that advice.

4. (1) If -

(a) the appropriate committee was consulted under paragraph 1 of this Schedule;

(b) the committee did not give a provisional opinion under paragraph 2(1) of this Schedule; and

(c) the licensing authority propose –

(i) to determine the matter in a way which differs from the advice of the committee, or

(ii) to suspend, revoke or vary the licence on grounds not relating to safety, quality or efficacy,

the authority shall notify the holder of the licence accordingly.

(2) A notification given under sub-paragraph (1) of this paragraph shall state -

(a) the advice of the committee and the reasons stated by the committee for that advice; and

(b) the proposals of the licensing authority and the reasons for them.

5. (1) Subject to sub-paragraph (4) of this paragraph, a person to whom a notification has been given under paragraph 3(2) of this Schedule may, within the time allowed, notify the licensing authority that he wishes to appear before and be heard by a person appointed by the licensing authority with respect to the decision.

(2) A person to whom a notification has been given under paragraph 4(1) of this Schedule may, within the time allowed -

(a) notify the licensing authority that he wishes to appear before and be heard by a person appointed for the purpose by the licensing authority, or

(b) make representations in writing to the licensing authority with respect to the proposal referred to in the notification.

(3) If the applicant makes written representations in accordance with sub-paragraph (2)(b) of this paragraph, the licensing authority shall take those representations into account before determining the matter.

(4) Sub-paragraph (1) of this paragraph shall not apply where –

(a) the person has not made any representations in accordance with paragraph 2(4) to (7) of this Schedule; and

(b) the decision of the licensing authority was in accordance with the advice of the appropriate committee.

Procedure in other cases

6. (1) This paragraph applies where the licensing authority propose, in the exercise of the powers conferred by section 28 of this Act -

(a) to suspend, revoke or vary a licence under Part 2 of this Act, other than a product licence; or

(b) to suspend, revoke or vary a product licence where the holder of the licence has been given neither –

(i) notice of any provisional opinion or any advice of the appropriate committee which led to that proposal under paragraphs 2 and 3 of this Schedule; nor

(ii) notice of that proposal under paragraph 4 of this Schedule,

and the provisions of paragraph 8 of this Schedule do not apply.

(2) The licensing authority shall notify the holder of the licence of –

(a) their proposals;

(b) the reasons for them; and

(c) the date (not being earlier than twenty-eight days from the date of the notification) on which it is proposed that the suspension, revocation or variation should take effect.

(3) The holder of the licence may, before the date specified in the notification –

(a) notify the licensing authority of his wish to appear before and be heard by a person appointed by the licensing authority with respect to the decision; or

(b) make representations in writing to the licensing authority with respect to the proposal referred to in the notification.

(4) If the applicant makes written representations in accordance with sub-paragraph (3)(b) of this paragraph, the licensing authority shall take those representations into account before determining the matter.

Hearing before person appointed

7. (1) If the holder of the licence gives notice under paragraph 5 or 6 of this Schedule of his wish to appear before and be heard by a person appointed by the licensing authority, the authority shall -

(a) make that appointment; and

(b) arrange for the applicant to have an opportunity of appearing before that person.

(2) The person appointed –

(a) shall not be, or at any time have been, a member of –

(i) the Commission on Human Medicines or any of its Expert Advisory Groups,

(ii) the Medicines Commission formerly established under section 2 of this Act or any of its committees, or

(iii) a committee established under section 4 of this Act, or any sub-committee of such a committee; and

(b) shall not be an officer or servant of any Minister of the Crown.

(3) Subject to sub-paragraph (4) of this paragraph, the holder of the licence shall provide the person appointed with –

(a) a written summary of the oral representations he intends to make; and

(b) any documents on which he wishes to rely in support of those representations,

before the end of the period of three months beginning with the date of the notice referred to in sub-paragraph (1) of this paragraph.

(4) If the holder of the licence so requests, the person appointed may, after consulting the licensing authority, extend the time limit referred to in sub-paragraph (3) of this paragraph, up to a maximum period of six months beginning with the date of the notice referred to in sub-paragraph (1) of this paragraph.

(5) If the holder of the licence fails to comply with the time limit in sub-paragraph (3) of this paragraph, or, where he has been granted an extended time limit under sub-paragraph (4) of this paragraph, that time limit –

(a) he may not appear before or be heard by the person appointed, and

(b) the licensing authority shall decide whether to grant or refuse the licence, or to grant it otherwise than in accordance with the application, and notify the applicant accordingly.

(6) The holder of the licence may not submit any additional written representations or documents once the time limit has expired, except with the permission of the person appointed.

(7) At the hearing before the person appointed, both the holder of the licence and the licensing authority may make representations.

(8) If the holder of the licence so requests the hearing shall be in public.

(9) After the hearing –

(a) the person appointed shall provide a report to the licensing authority; and

(b) the licensing authority shall take this report into account and decide whether to revoke, vary or suspend the licence.

(10) The licensing authority shall then -

(a) notify the holder of the licence of their decision;

(b) if the holder so requests, provide the holder with a copy of the report of the person appointed.

Procedure in cases of urgency

8. Notwithstanding anything in paragraphs 1 to 7 of this Schedule, where it appears to the licensing authority that in the interests of safety it is necessary to suspend a licence under Part 2 of this Act with immediate effect, the licensing authority may do so, for a period not exceeding three months.

9. If the licence is a product licence, the licensing authority shall report the suspension forthwith to the appropriate committee.

10. If, after the suspension has taken effect –

(a) it appears to the licensing authority; or

(b) in the case of a product licence, they are advised by the appropriate committee,

that it is necessary to consider whether the licence ought to be further suspended, or ought to be revoked or varied, the licensing authority (subject to paragraph 11 of this Schedule) shall proceed in accordance with such of the provisions of paragraphs 1 to 7 of this Schedule as are applicable in the circumstances.

11. (1) This paragraph applies where, in the circumstances specified in paragraph 10 of this Schedule, the licensing authority proceed as mentioned in that paragraph and any proceedings under paragraphs 1 to 7 of this Schedule relating to a further suspension of the licence have not been finally disposed of before the end of the period –

(a) for which the licence was suspended under paragraph 8 of this Schedule; or

(b) for which it has been further suspended under this paragraph.

(2) If it appears to the licensing authority to be necessary in the interests of safety to do so, the authority may further suspend the licence for a period which (in the case of each such further suspension) shall not exceed three months.

(3) The provisions of section 27(7) of this Act shall, with the necessary modifications, have effect for the purpose of determining the date on which any proceedings are taken to be finally disposed of.

Interpretation

12. In this Schedule, the "the time allowed" means the period of twenty-eight days from the date of the relevant notification, or such longer period as the licensing authority may allow in any particular case.

SCHEDULE 3

Sampling

Introductory

1. (1) The provisions of this Schedule shall have effect where a person authorised in that behalf by an enforcement authority (in this Schedule referred to as a "sampling officer") obtains a sample of any substance or article

(a) for the purpose of ascertaining whether there is or has been, in connection with that substance or article, any contravention of any provisions of this Act or of any regulations or order made thereunder which, by or under any provisions of sections 108 to 110 of this Act, that authority (in this Schedule referred to as "the relevant enforcement authority") is required or empowered to enforce, or

(b) otherwise for any purpose connected with the performance by that authority of their functions under this Act or under any such regulations or order,

and the sampling officer obtains the sample by purchase or in the exercise of any power conferred by section 112 of this Act.

(2) In this Schedule "public analyst", [F197except in relation to Northern Ireland, has the meaning assigned to it by section 27 of the Food Safety Act 1990], and in relation to Northern Ireland has the meaning assigned to it by [F198Article 27(1) of the Food Safety (Northern Ireland) Order 1991].

Division of sample

2. The sampling officer shall forthwith divide the sample into three parts, each part to be marked and sealed or fastened up in such manner as its nature will permit.

3. If the sample was purchased by the sampling officer, otherwise than from an automatic machine, he shall supply one part of the sample to the seller.

4. If the sampling officer obtained the sample from an automatic machine, then -

(a) if a person's name, and an address in the United Kingdom, are stated on the machine as being the name and address of the owner of the machine, the sampling officer shall supply one part of the sample to that person;

(b) in any other case, the sampling officer shall supply one part of the sample to the occupier of the premises on which the machine stands or to which it is affixed.

5. If the sample is of goods consigned from outside the United Kingdom and was taken by the sampling officer before delivery to the consignee, the sampling officer shall supply one part of the sample to the consignee.

6. If, in a case not falling within any of paragraphs 3 to 5 of this Schedule, the sample was obtained by the sampling officer at the request or with the consent of a purchaser, the sampling officer shall supply one part of the sample to the seller.

7. If, in a case not falling within any of paragraphs 3 to 6 of this Schedule, the sample was taken in transit, the sampling officer shall supply one part of the sample to the consignor.

8. In any case not falling within any of paragraphs 3 to 7 of this Schedule the sampling officer shall supply one part of the sample to the person appearing to him to be the owner of the substance or article from which the sample was taken.

9. In every case falling within any of paragraphs 3 to 8 of this Schedule the sampling officer shall inform the person to whom the part of the sample in question is supplied that the sample has been obtained for the purpose of analysis or other appropriate examination.

10. Of the remaining parts of the sample into which the sample is divided in accordance with paragraph 2 of this Schedule, the sampling officer, unless he decides not to submit the sample for analysis or other appropriate examination, shall –

(a) retain one part for future comparison, and

(b) submit the other part for analysis or examination in accordance with the following provisions of this Schedule.

11. Where a sample consists of substances or articles enclosed in unopened containers, and it appears to the sampling officer that to open the containers and divide the contents into parts –

    (a) is not reasonably practicable, or

    (b) might affect the composition or impede the proper analysis or other examination of the contents,

    the sampling officer may divide the sample into parts by dividing the containers into three lots without opening them.

12. Section 127 of this Act shall have effect in relation to supplying any part of a sample in pursuance of the preceding paragraphs as it has effect in relation to the service of a document.

13. If after reasonable inquiry the sampling officer is unable to ascertain the name of a person to whom, or the address at which, a part of a sample ought to be supplied in pursuance of the preceding paragraphs, he may retain that part of the sample instead of supplying it.

Notice to person named on container

14. (1) Where it appears to the sampling officer that a substance or article of which he has obtained a sample was manufactured or assembled by a person whose name and address in the United Kingdom are stated on its container, and who is not a person to whom a part of the sample is required to be supplied under the preceding provisions of this Schedule, the sampling officer, unless he decides not to submit the sample for analysis or other appropriate examination, shall serve notice on that person

    (a) stating that the sample has been obtained by the sampling officer, and

    (b) specifying the person from whom the sampling officer purchased it, or, if he obtained it otherwise than by purchase, the place from which he obtained it.

    (2) The notice required to be served under the preceding sub-paragraph shall be served before the end of the period of three days beginning with the day on which the sample was obtained.

Analysis or other examination of sample

15. If the sampling officer decides to submit the sample for analysis or other appropriate examination, he shall –

    (a) submit it for analysis to the public analyst for the area in which the sample was obtained, or, if for the time being there is no public analyst for that area, then to the public analyst for some other area, or

    (b) submit it for other appropriate examination to the person having the management or control of any laboratory available for the purpose in accordance with any arrangements made in that behalf by the relevant enforcement authority.

16. Where the relevant enforcement authority is a Minister or the Pharmaceutical Society, and the sampling officer decides to have the sample analysed, he may (instead of submitting it to a public analyst) submit it for analysis to the person having the management or control of any laboratory available for the purpose in accordance with any arrangements made in that behalf by the relevant enforcement authority.

17. Any such arrangements as are mentioned in paragraph 15(b) or paragraph 16 of this Schedule,

    (a) …;

    (b) if … they are made by an enforcement authority in England and Wales other than the Secretary of State, shall be arrangements approved by the Secretary of State;

    (c) if they are made by an enforcement authority in Scotland other than the Secretary of State, shall be arrangements approved by the Secretary of State;

    and any such arrangements as are mentioned in paragraph 15(b) of this Schedule, if made by a district council in Northern Ireland, shall be arrangements approved by the Minister of Health and Social Services for Northern Ireland.

18. (1) Subject to the following sub-paragraph, the person to whom the sample is submitted under paragraph 15 or paragraph 16 of this Schedule shall analyse or examine the sample (as the case may be), or cause the sample to be analysed or examined by some other person under his direction, as soon as practicable.

    (2) If the person to whom the sample is so submitted is a public analyst, and that analyst determines that for any reason an effective analysis of the sample cannot be performed by him or under his direction, he shall send it to the public analyst for some other area, and that other public analyst shall as soon as practicable analyse the sample or cause it to be analysed by some other person under his direction.

19. (1) A public analyst who has analysed a sample submitted to him under the preceding provisions of this Schedule, or who has caused such a sample to be analysed by some other person under his direction, shall issue and send to the sampling officer a certificate specifying the result of the analysis.

    (2) A person having the management or control of a laboratory in which a sample submitted to him under the preceding provisions of this Schedule has been analysed or examined, or a person appointed by him for the purpose, shall issue and send to the sampling officer a certificate specifying the result of the analysis or examination.

    (3) Any certificate issued under this paragraph shall be in a form prescribed by the Ministers and shall be signed by the person who issues the certificate.

20. (1) Any person to whom, in accordance with paragraphs 2 to 8 of this Schedule, a part of the sample is required to be supplied shall, on payment of the prescribed fee to the relevant enforcement authority, be entitled to be supplied with a copy of any certificate as to the result of an analysis or examination which is sent to the sampling officer under paragraph 19 of this Schedule.

    (2) Any regulations prescribing a fee for the purposes of this paragraph shall be made by the Ministers.

Provisions as to evidence

21. In any proceedings for an offence under this Act a document produced by one of the parties to the proceedings and purporting to be a certificate issued under paragraph 19 of this Schedule shall be sufficient evidence of the facts stated in the document, unless the other party requires that the person who issued the certificate shall be called as a witness; and, in any proceedings in Scotland, if that person is called as a witness, his evidence shall be sufficient evidence of those facts.

22. In any proceedings for an offence under this Act a document produced by one of the parties to the proceedings, which has been supplied to him by the other party as being a copy of such a certificate, shall be sufficient evidence of the facts stated in the document.

23. (1) If in any such proceedings before a magistrates· court a defendant intends to produce such a certificate, or to require that the person by whom such a certificate was issued shall be called as a witness, a notice of his intention, and (where he intends to produce such a certificate) a copy of the certificate, shall be given to the other party at least three clear days before the day on which the summons is returnable.

(2) If the preceding sub-paragraph is not complied with, the court may, if it thinks fit, adjourn the hearing on such terms as it thinks proper.

(3) In Scotland, if in any such proceedings in the sheriff court the accused intends to produce such a certificate, or to require that the person by whom such a certificate was issued shall be called as a witness, notice of his intention, and (where he intends to produce such a certificate) a copy of the certificate, shall be given to the procurator fiscal at least three clear days before the day on which the case proceeds to trial.

(4) If sub-paragraph (3) of this paragraph is not complied with, the sheriff may, if he thinks fit, adjourn the diet on such terms as he deems proper.

Analysis under direction of court

24. (1) In any proceedings for an offence under this Act, where the proceedings relate to a substance or article of which a sample has been obtained as mentioned in paragraph 1 of this Schedule, the part of the sample retained in pursuance of paragraph 10(a) of this Schedule shall be produced as evidence; and the court –

(a) at the request of either party to the proceedings shall, and

(b) in the absence of any such request may if it thinks fit,

cause that part of the sample to be sent for analysis to the Government Chemist (or, in Northern Ireland, the Government Chemist for Northern Ireland) or to be sent for other appropriate examination to the person having the management or control of a laboratory specified by the court.

(2) If, in a case where an appeal is brought, no action has been taken under the preceding sub-paragraph, the provisions of that sub-paragraph shall have effect in relation to the court by which the appeal is heard.

(3) A person to whom a part of a sample is sent under this paragraph for analysis or other examination shall analyse or examine it, or cause it to be analysed or examined on his behalf, and shall transmit to the court a certificate specifying the result of the analysis or examination.

(4) Any such certificate shall be signed by that person, or signed on his behalf by the person who made the analysis or examination or a person under whose direction it was made.

(5) Any such certificate shall be evidence (and, in Scotland, shall be sufficient evidence) of the facts stated in the certificate unless any party to the proceedings requires that the person by whom it was signed shall be called as a witness; and, in any proceedings in Scotland, if that person is called as a witness, his evidence shall be sufficient evidence of those facts.

25. The costs of any analysis or examination under paragraph 24 of this Schedule shall be paid by the prosecutor or the defendant (or, in Scotland, the accused) as the court may order.

Proof by written statement

26. In relation to England and Wales section 9 of the Criminal Justice Act 1967, and in relation to Northern Ireland any corresponding enactment which may be passed by the Parliament of Northern Ireland, shall not have effect with respect to any document produced as mentioned in paragraph 21 or paragraph 22 of this Schedule or with respect to any certificate transmitted to a court under paragraph 24 of this Schedule.

Power to modify sampling provisions

27. The Ministers may by order provide that, in relation to substances or articles of any such description as may be specified in the order, the preceding provisions of this Schedule shall have effect subject to such exceptions and modifications as may be specified in the order.

Payment for sample taken under compulsory powers

28. (1) Where a sampling officer takes a sample in the exercise of any power conferred by section 112 of this Act he shall, if payment is demanded, pay the value of the sample to the person to whom a part of the sample is required under paragraph 5, paragraph 7 or paragraph 8 of this Schedule (as the case may be) to be supplied.

(2) In default of agreement between the sampling officer and the person mentioned in the preceding sub-paragraph, the value of the sample shall be determined by the arbitration of a single arbitrator appointed by the sampling officer and the other person in question or, if they are unable to agree on the appointment of an arbitrator, shall be determined by the county court for the district (or, in Northern Ireland, the division) in which the sample was taken.

Application of s. 64 to samples

(3) In the application of this paragraph to Scotland, for references to an arbitrator there shall be substituted references to an arbiter and for the reference to the county court there shall be substituted a reference to the sheriff.

29. Where a medicinal product is taken as a sample by a sampling officer in the exercise of any power conferred by section 112 of this Act, the provisions of subsections (1) to (4) of section 64 of this Act shall have effect as if the taking of the product as a sample were a sale of it to the sampling officer by the person from whom it is taken; and, if the product was prepared in pursuance of a prescription given by a practitioner, those provisions shall so have effect as if, in subsection (1) of that section, for the words ”demanded by the purchaser”, there were substituted the words ”specified in the prescription”.

SCHEDULE 4

Section 134.

Provisions Relating To Northern Ireland

1. (1) The Minister of Health and Social Services for Northern Ireland may by order make provision for the application of this Act in relation to druggists subject to such exceptions and modifications as may be specified in the order.

   (2) In this paragraph ”druggist” means a person registered in the register of druggists for Northern Ireland made out and maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976.

2. ….

3. ….

4. ….

5. ….

6. The appropriate Northern Ireland Minister … may in relation to Northern Ireland exercise any power of making an order or regulations which is conferred on the … Ministers by any provision of this Act (except a provision contained in section 15(3),. . . or section 57(3) of this Act) where in his … opinion there are special circumstances which render it expedient to do so.

7. ….

8. Every order or regulation under this Act made by the Minister of Health and Social Services for Northern Ireland… by virtue of the power conferred by paragraph 1, … or paragraph 6 of this Schedule, and every regulation made solely by the Minister of Health and Social Services for Northern Ireland under section 120 of this Act, shall be subject to negative resolution within the meaning of section 41(6) of the [M48]Interpretation Act (Northern Ireland) 1954 as if it were a statutory instrument within the meaning of that Act.

9. In this Schedule ”the appropriate Northern Ireland Minister …” –

   (a) … means the Minister of Health and Social Services for Northern Ireland;

   (b) …

   (c) …

   ….

10. In this Act any reference to the Minister of Health and Social Services for Northern Ireland … and any reference which is to be construed as including a reference to that Ministers, shall include a reference to the Ministry of Health and Social Services for Northern Ireland ….

11. The Statutory Rules (Northern Ireland) Order 1979, except article 5(2)(*a*) of that Order] (which requires the responsible officer of each rule-making authority making any statutory rules to send copies of them, and certain information, to the Ministry of Finance for Northern Ireland for registration under that Order), shall not apply to any orders or regulations made under this Act by statutory instrument.

SCHEDULE 5

Section 135(1)

Amendments of Enactments of Parliament of United Kingdom

1. The Venereal Disease Act 1917 (c. 21).

   In the proviso to section 2 (restriction on advertisements relating to treatment for venereal disease), for the words ”announcement, recommendation, or holding out” there shall be substituted the words ”or announcement”.

2 - 9. …

10. The Cancer Act 1939 (c. 13.)

    In section 4, in subsection (4)(a)(v), for the words ”authorised sellers of poisons” there shall be substituted the words ”persons lawfully conducting a retail pharmacy business in accordance with section 69 of the Medicines Act 1968”.

11- 15. ...

16. The Trade Descriptions Act 1968 (c. 29).

    In section 2, in subsection 5, after the word ”section” there shall be inserted ”(a)”, and at the end of the subsection there shall be inserted the following paragraph:

    “(b) where by virtue of any provision made under Part V of the Medicines Act 1968 (or made under any provisions of the said Part V as applied by an order made under section 104 or section 105 of that Act) anything which, in accordance with this Act, constitutes the application of a trade description to goods is subject to any requirements or restrictions imposed by that provision, any particular description specified in that provision, when applied to goods in circumstances to which those requirements or restrictions are applicable, shall be deemed not to be a trade description.”

17. In section 22, in subsection (2), after the words ”the Food and Drugs Act (Northern Ireland) 1958“ there shall be inserted the words ”or the Medicines Act 1968” ; in paragraph (b) the word ”and”, where it occurs at the end of that paragraph, shall be omitted ; and at the end of paragraph (c) there shall be inserted the words:

    “and

    (d) in relation to the said Act of 1968, so much of Schedule 3 to that Act as is applicable to the circumstances in which the sample was procured,”

    at the end of the subsection there shall be inserted the words “or paragraph 27 of Schedule 3 to the said Act of 1968”.

Section 135(2)

Enactments of Parliament of United kingdom Repealed

Section 135(2).

SCHEDULE 6

ENACTMENTS OF PARLIAMENT OF UNITED KINGDOM REPEALED

Chapter	Short Title	Extent of Repeal
7 & 8 Geo. 5. c. 21.	The Venereal Disease Act 1917.	Section 2(2), except the proviso.
23 & 24 Geo. 5. c. 25.	The Pharmacy and Poisons Act 1933.	Sections 8 to 14. In section 17, in subsection (2), the words ' of persons who are to be entitled to sell poisons in Part II ', and, in subsection (6), the words from ' and in this Act ' to the end of the subsection. In section 18(2)(*a*)(ii) the word " registered ". Section 19. In section 23, in subsection (1), paragraph (*a*), paragraph (*b*) (ii) and paragraph (*f*); and in subsection (3), in the reference to paragraphs (*a*), (*b*)(i), (*c*), (*d*), (*e*) and (*f*), the references to paragraphs (*a*) and (*f*). In section 25, in subsection (1) the words ' Part I of this Act and of section nineteen and ', in subsection (4) those words and the word ' registered ', and subsection (9). In section 29, the definitions of ' authorised seller of poisons ' and ' poison ' and paragraph (*a*) of the definition of ' registered '
2 & 3 Geo. 6. c. 13.	The Cancer Act 1939.	In section 4, subsection (1)(*b*), subsection (3) and subsection (4)(*a*)(vii).
4 & 5 Geo. 6. c. 42.	The Pharmacy and Medicines Act 1941.	The whole Act.
11 & 12 Geo. 6. c. 37.	The Radioactive Substances Act 1948.	Sections 3 and 4. In section 12, the definition of ' authorised seller of poisons '.

Chapter	Short Title	Extent of Repeal
14 Geo. 6. c. 36.	The Diseases of Animals Act 1950.	Part II and Schedule 3.
2 & 3 Eliz. 2. c. 61.	The Pharmacy Act 1954.	Section 19.
4 Eliz. 2. c. 16.	The Food and Drugs Act 1955.	In section 1, subsection (2) and subsection (3)(*b*). In section 2(3), the words from " except " to " drugs ". Section 3(2). In section 6(6), the words from " except " to " drugs ". In section 91(2), the words from " but " to the end of the subsection. In section 109(3)(*a*), the words from " so " to the end of the paragraph. In section 114(4), the words from 'the authority concerned' to 'in any other case'. The words " or drug " and " drug " wherever they occur, except in section 135. In Schedule 8, in column 2, in the first paragraph, the words from " other " to " drug ". In Part I of Schedule 9, in column 2, paragraph (*a*)(iii) of the definition relating to sections 321 to 325 of the Public Health Act 1936.
4 & 5 Eliz. 2. c. 25.	The Therapeutic Substances Act 1956.	The whole Act.
4 & 5 Eliz. 2. c. 30.	The Food and Drugs (Scotland) Act 1956.	In section 1, subsection (2) and subsection (3)(*b*). In section 2(3) the words from " except " to " drugs ". Section 3(2). In section 6(6) the words from " except " to " drugs ". In section 28(2) the words from " but " to the end of the subsection. The words " or drug " and " drug " wherever they occur, except in section 58.
4 & 5 Eliz. 2. c. 76.	The Medical Act 1956.	Section 47. Section 57(9) and (10).
1963 c. 9.	The Purchase Tax Act 1963.	In Part II of Schedule 1, in paragraph 5(2), the definition of 'authorised seller of poisons'.

SCH. 6

Chapter	Short Title	Extent of Repeal
1964 c. 64.	The Drugs (Prevention of Misuse) Act 1964.	In section 1, in subsection (7), the reference to, and the paragraph substituted for, paragraph (*k*) of subsection (2). In section 9 the definition of ' authorised seller of poisons '.
1965 c. 15.	The Dangerous Drugs Act 1965.	In section 11, in subsection (4) the words ' in subsection (1) thereof '.

SCHEDULE 7

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Section 135(4)

Enactments of Parliament of Northern Ireland Repealed

SCHEDULE 8

Section 135(4).

ENACTMENTS OF PARLIAMENT OF NORTHERN IRELAND REPEALED

Session or Year and Chapter	Short Title	Extent of Repeal
15 & 16 Geo. 5. c. 8 (N.I.).	The Pharmacy and Poisons Act (Northern Ireland) 1925.	Section 17. Section 18. Schedule 3.
1945 c. 9 (N.I.).	The Medicines, Pharmacy and Poisons Act (Northern Ireland) 1945.	Part I. In section 14, in subsection (1) the words " if he is a registered person " and the words from " and, if he is a representative " onwards; and in subsection (2) the proviso. Sections 15 to 18. In section 19, in subsection (1) the words " or to be an authorised seller of poisons " and the words from " , or if the owner is a body corporate " to " employee of the body corporate,"; in subsection (2) in paragraph (*a*) the words from " or, if the owner " onwards and in paragraph (*b*) the words from " or, if the owner is a body corporate " to " employee of the body corporate,"; and subsection (3). In section 27(1)(*a*)(iii) the words from " in accordance " onwards. Section 28. In section 32, in subsection (1) paragraphs (*a*), (*b*)(ii) and (*i*), and in subsection (3) the references to paragraphs (*a*) and (*i*) of subsection (1) In section 35(3) the words " section four, section five or ". In section 36(2) and (3) the words " I and ". Section 37. In section 38(1) the definitions of " authorised seller of poisons ", " poison ", " premises having an annual licence " and " retailing ". In Schedule 2 in the proviso to paragraph (1) the word " or " at the end of paragraph (*a*) and paragraphs (*b*) and (*c*).

SCH. 8

Session or Year and Chapter	Short Title	Extent of Repeal
1955 c. 31 (N.I.).	The Pharmacy and Poisons Act (Northern Ireland) 1955.	Section 2. Section 14.
1958 c. 13 (N.I.).	The Diseases of Animals Act (Northern Ireland) 1958.	Part II. In Schedule 4, Part I.
1958 c. 27 (N.I.).	The Food and Drugs Act (Northern Ireland) 1958.	In section 1 subsection (2), subsection (3)(*b*) and in subsection (6) the words " or drug ". In section 2 in subsection (1) the words " or drug " in both places where they occur, and in subsection (3) the words " , except so far as it relates to drugs,". Section 3(2). In section 6 in subsection (1) the words " or drug " in each of the three places where they occur, in subsection (2) those words in each of the two places where they occur, in subsection (5) those words and in subsection (6) the words " , except so far as it relates to drugs,". In section 33 in subsection (2) the words " or drug " and subsection (3). In section 34 in subsection (1) the word " , drug " and in subsection (2) the words " or drug ". In section 35 in subsections (1) and (4) the word " , drug ". In section 38 the word ", drug " in both places where it occurs. In section 44 in subsection (2)(*a*) the word " , drug " in both places where it occurs and in subsection (3) that word in both places where it occurs. In section 47, in subsection (1) the words " so far as those sections or regulations relate to food ", and in subsection (3)(*a*) the words " so far as it relates to food ".
1966 c. 23 (N.I.).	The Diseases of Animals (Amendment) Act (Northern Ireland) 1966.	Section 3(2).

Session or Year and Chapter	Short Title	Extent of Repeal
1967 c. 12 (N.I.).	The Pharmacy Act (Northern Ireland) 1967.	Section 5. In Schedule 1 the entries amending sections 17 and 27 of the Pharmacy and Poisons Act (Northern Ireland) 1925 and the entries amending the proviso to section 14(2) and sections 15, 16, 17 and 18 of, and paragraph 1 of Schedule 2 to, the Medicines, Pharmacy and Poisons Act (Northern Ireland) 1945.
1967 c. 29 (N.I.).	The Increase of Fines Act (Northern Ireland) 1967.	In the Schedule the entries relating to sections 15(4) and 16(1A) of the Medicines, Pharmacy and Poisons Act (Northern Ireland) 1945 and Section 32 of the Diseases of Animals Act (Northern Ireland) 1958.

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