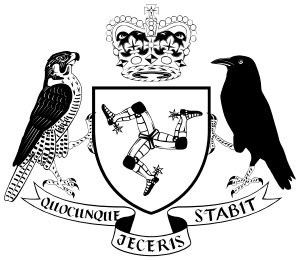


Isle of Man

*Ellan Vannin*

**AT 4 of 2003**

# MEDICINES ACT 2003

Isle of Man

*Ellan Vannin*

# MEDICINES ACT 2003

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Isle of Man

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# MEDICINES ACT 2003

| | |
|---|---|
| *Received Royal Assent:* | *8 April 2003* |
| *Passed:* | *8 April 2003* |
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**AN ACT** to make new provision for regulating the import, manufacture, sale and supply of and other dealings with medicinal products and veterinary medicinal products; and for connected purposes.

## PART 1 – DEALINGS WITH MEDICINAL PRODUCTS

### 1 Introductory

[OJ L 311, 28.11.01; OJ L 214, 24.8.93]

(1) In exercising its functions under this Part the Department of Health and Social Care ("the Department") shall have regard to the systems of control of dealings with medicinal products for the time being operating in the United Kingdom.[1]

(2) In this Act "**medicinal product**" means —

(a) any substance or combination of substances presented for treating or preventing disease in human beings; or

(b) any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings.

(3) In this Act —

"**Community authorisation**" [Repealed][2]

"**EU authorisation**" means a marketing authorisation granted or renewed by the European Commission under the EC Regulation;[3]

"**UK authorisation**" means —

(a) a marketing authorisation granted or recognised as having effect as a UK marketing authorisation in accordance with the Human Medicines Regulations 2012 (of Parliament)[1];[4]

(b) a certificate of registration for a registrable homoeopathic medicinal product granted in accordance with the Human Medicines Regulations 2012 (of Parliament)[2];[5]

(c) a product licence granted in the United Kingdom under section 7 of the UK Act (a "product licence");

(d) a manufacturer's licence granted in the United Kingdom under section 8(2) of the UK Act;

(e) a clinical trial certificate issued in the United Kingdom under section 31 of the UK Act.

(4) The Department may by regulations amend the definitions in subsection (3).

## 2 Restrictions on dealing with medicinal products

(1) The Department shall by regulations make provision for controlling, restricting, regulating or prohibiting the following activities —

(a) selling, supplying or otherwise placing on the market any medicinal product;

(b) manufacturing or assembling any medicinal product;

(c) distributing any medicinal product;

(d) procuring the sale, supply or placing on the market otherwise than by sale or supply, manufacture, assembly or distribution of any medicinal product;

(e) the import or export of any medicinal product;

(f) possessing any medicinal product, with a view to administering, selling or supplying it or otherwise placing it on the market;[6]

(g) administering any medicinal product.[7]

(2) Regulations under subsection (1) may impose such requirements as the Department considers necessary or expedient for any of the purposes specified in subsection (3) with respect to —

(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;

(d) the supply with medicinal products of leaflets;

[1] SI 2012/1916

[2] SI 2012/1916

(e) the strength, materials, shape or other characteristics of containers of medicinal products.

(3) The purposes referred to in subsection (2) 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; and

(d) in relation to subsection (2)(e), preserving the quality of medicinal products.

(4) Regulations under this section —

(a) shall provide for giving effect in the Island, in such circumstances and subject to such conditions as may be prescribed, to UK authorisations; and[8]

(b) may provide for giving effect in the Island, subject to such conditions as may be prescribed, to EU authorisations and to any other authorisation licence, consent, certificate or other document relating to any activity mentioned in subsection (1) and granted or issued in the EU under any EU instrument.[9]

## 3 Exemptions

(1) The Department shall by regulations provide for the exemption, in such circumstances and subject to such conditions as are prescribed, from any control, restriction, regulation or prohibition imposed under section 2(1) or section 5, for —

(a) prescribed activities in the course of his profession of a practitioner;

(b) prescribed activities in a registered pharmacy, a hospital or a health centre of, or under the supervision of, a pharmacist.[10]

(2) The Department may by regulations provide for further exemptions, in such circumstances and subject to such conditions as are prescribed, from any such control, restriction, regulation or prohibition.

## 4 General sale of medicinal products

(1) This section applies to any medicinal product, except one which under the terms of an authorisation may be sold or supplied otherwise than by, or under the supervision of, a pharmacist.[11]

(2) Regulations under section 2 shall prohibit, except in such circumstances and subject to such conditions as may be prescribed, any person, in the course of a business carried on by him, selling by retail, offering or

exposing for sale by retail, or supplying in circumstances corresponding to retail sale, any medicinal product to which this section applies 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.

(3) Subsection (2) is without prejudice to the generality of section 2, and does not preclude the making of any other provision under that section with respect to any medicinal product to which this section applies.

## 5 Medicinal products on prescription only

(1) This section applies to medicinal products which under the terms of an authorisation are not to be sold by retail except in accordance with a prescription given by a person holding specified qualifications or complying with specified conditions.[12]

(2) No person shall —

(a) sell by retail, offer or expose for sale by retail or supply in circumstances corresponding to retail sale, a medicinal product to which this section applies unless it is sold or supplied in accordance with a prescription given by an appropriate practitioner; or

(b) administer (otherwise than to himself) any medicinal product to which this section applies unless he is an appropriate practitioner or a person acting in accordance with the directions of an appropriate practitioner.

This is subject to regulations made under section 2, 3 or 52.[13]

(2A) Subsection (2)(a) does not apply to the sale or supply of a medicinal product to a patient of his by a doctor or dentist who is an appropriate practitioner.[14]

(2B) For the purposes of this section, "appropriate practitioner" means a practitioner referred to in paragraph (a) of the definition of "practitioner" in Schedule 2.[15]

(3) Subsection (2) is without prejudice to the generality of section 2, and does not preclude the making of any other provision under that section with respect to any medicinal product to which this section applies.

## 5A Offences

Any person who, —

(a) contravenes section 5(2); or

(b) has in his possession a medicinal product to which section 5 applies and which he intends to sell, supply or administer in contravention of that section,

shall be guilty of an offence and liable, —

(i) on summary conviction, to a fine not exceeding level 5 on the standard scale;

(ii) on conviction on information, to custody for a term not exceeding 2 years or to a fine, or to both.[16]

## 6 Regulations: general provisions

(1) Regulations under this Part may provide that any person contravening a specified requirement of the regulations is guilty of an offence and liable —

(a) on summary conviction to a fine not exceeding such amount (which shall not exceed £5,000) as may be specified in the regulations; and

(b) if the regulations so provide, on conviction on information to custody for a term not exceeding 2 years or to a fine, or to both.

(2) Regulations under this Part may —

(a) require —

(i) as a condition for carrying on any activity to which the regulations relate, or

(ii) as a condition for any exemption conferred under section 3,

any person to be entered in a register kept, or the holder of a licence or certificate issued, by a prescribed person or authority for the purpose of the regulations, or any premises to be entered in a register so kept;

(b) impose conditions in respect of the entry or retention of persons or premises in such a register, or the issue of such a licence or certificate, including conditions requiring the payment of fees;

(c) make provision as to —

(i) applications for entry or retention in such a register, or the issue or renewal of such a licence or certificate,

(ii) the making of entries in the register or the issue of such a licence or certificate,

(iii) the duration, renewal, suspension and revocation of registration, licences or certificates;

(iv) reviews of, and appeals to a prescribed authority against, any decision relating to registration, licences or certificates.

(3) Before making any regulations under this Part the Department shall consult —

(a) any profession appearing to the Department to be substantially affected by the regulations, and

(b) such organisations as appear to the Department to be representative of other interests likely to be substantially affected by the regulations;

and section 41 of the *National Health Service Act 2001* applies to consultations under paragraph (a) as it applies to consultations for the purposes of that Act.

## PART 2 – CONSUMER PROTECTION

### 7 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.

### 8 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) No person shall sell or supply, in pursuance of a prescription given by a practitioner, any medicinal product which is not of the nature or quality specified in the prescription.

(3) Subsection (1) or (2) 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) or (2) 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) 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.

## 9 Compliance with published standards

(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, or is an approved synonym for, 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, or is an approved synonym for, 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 (2), 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), in this section —

"publication" means —

(a) the European Pharmacopoeia,

(b) the British Pharmacopoeia,

(c) the British Pharmaceutical Codex, or

(d) any compendium published under Part VII of the UK 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, or by a name for which it is an approved synonym, 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 by a name for which it is an approved synonym, or, in default of such a monograph, means the monograph headed by that name or by a name for which it is an approved synonym 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);

"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 (2).

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

(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

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

(c) 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 the UK Act; or

(d) 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 (7), 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)); 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) 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, together with any amendments, additions and deletions made to it which, by notice published in the London Gazette under section 65(7) of the UK Act before the time referred to in subsection (4), have been declared to have effect for the purposes of the said section 65); 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, 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 Medicines Commission in the United Kingdom as a synonym for that name.

## 10 Misleading descriptions etc

(1) 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.

(2) 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.

### 11 Display of information on automatic machines

(1) The Department may by regulations impose such requirements as it considers 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 subsection (1) which are applicable to that product.

### 12 Offences

(1) Any person who contravenes section 7, 8(1) or (2), 9(1) or (2) or 10(1) or (2) is guilty of an offence and liable —

(a) on summary conviction, to a fine not exceeding £5,000;

(b) on conviction of information, to custody for a term not exceeding 2 years or to a fine, or to both.

(2) Any person who contravenes section 11(2) is guilty of an offence and liable on summary conviction to a fine not exceeding £1,000.

## PART 3 – PROMOTION OF SALES OF MEDICINAL PRODUCTS

### 13 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 is guilty of an offence.

(2) Where —

(a) an authorisation applicable to medicinal products of a particular description is in force, and

(b) in accordance with the provisions of the authorisation, the purposes for which medicinal products of that description may be recommended to be used are limited to those specified in the authorisation,

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 an unauthorised recommendation is guilty of an offence.

(3) 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 is guilty of an offence.

(4) Any person who, in the course of a relevant 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,

is guilty of an offence.

(5) Where, in the circumstances specified in subsection (2), 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 subsection (4)(a) to (c), 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, is guilty of an offence.

(6) 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), (3) or (4), 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 (5), 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.

(7) Without prejudice to subsection (6), 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 —

(a) he is a person whose business it is to issue or arrange for the issue of advertisements, and

(b) either —

(i) 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 alterations except in respect of lettering or lay-out; or

(ii) 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

(c) he did not know and had no reason to suspect that the issue of the advertisement would amount to an offence under this section.

(8) 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.

(9) In this section "unauthorised recommendation", in relation to the circumstances specified in subsection (2), means a recommendation whereby medicinal products of a description to which the authorisation in question is applicable are recommended to be used for purposes other than those specified in the authorisation.

(10) Any person guilty of an offence under this section is liable —

(a) on summary conviction, to a fine not exceeding £5,000;

(b) on conviction on information, to custody for a term not exceeding 2 years or to a fine, or to both.

## 14 Advertisements requiring consent

(1) Where an authorisation is in force which is applicable to medicinal products of a particular description, then, except with the consent of the holder of the authorisation —

(a) no commercially interested party (other than the holder of the authorisation) 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) Any person who contravenes subsection (1) is guilty of an offence and liable on summary conviction to a fine not exceeding £1,000.

## 15 Regulation of advertisements and representations

(1) The Department may by regulations prohibit the issue, except in such circumstances and subject to such conditions as may be prescribed, of advertisements —

(a) relating to medicinal products of a description, or falling within a class, specified in the regulations;

(b) likely to lead to the use of any medicinal product, or any other substance or article, for the purpose of —

(i) treating or preventing a disease specified in the regulations,

(ii) diagnosis of a disease so specified,

(iii) ascertaining the existence, degree or extent of a physiological condition so specified,

(iv) permanently or temporarily preventing or otherwise interfering with the normal operation of a physiological function so specified, or

(v) artificially inducing a condition of body or mind so specified;

(c) 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);

(d) 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 Department, 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) Regulations under subsection (1)(b), (c) or (d) may prohibit the making of any representation —

(a) likely to lead to the use of a medicinal product or other substance or article to which the regulations apply for a purpose specified under subsection (1)(b), or

(b) containing a word or phrase specified in the regulations under subsection (1)(d),

if the representation —

(i) 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

(ii) 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

(iii) 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 subsection (1) and (2), the Department may, for any of the purposes specified in subsection (4), by regulations impose such requirements as it considers necessary or expedient with respect to —

(a) the particulars which advertisements relating to medicinal products must contain;

(b) the form of any such advertisements;

(c) in the case of advertisements by way of cinema 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) 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) Regulations under this section may provide that any person contravening a specified requirement of the regulations is guilty of an offence and liable —

(a) on summary conviction to a fine not exceeding such amount (which shall not exceed £5,000) as may be specified in the regulations; and

(b) if the regulations so provide, on conviction on information to custody for a term not exceeding 2 years or to a fine, or to both.

## 16 Advertisements and representations directed to practitioners

(1) No advertisement relating to medicinal products of a particular description, other than a product summary, 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) are fulfilled.

(2) 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) are fulfilled.

(3) Those conditions are —

(a) that a product summary 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 product summary has been sent or delivered to him not more than 15 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 product summary.

(4) Any person who contravenes subsection (1) or (2) is guilty of an offence and liable —

(a) if he contravenes that subsection by not complying with the condition specified in subsection (3)(b) —

(i) on summary conviction, to a fine not exceeding £5,000, or

(ii) on conviction on information to custody for a term not exceeding 2 years or to a fine, or to both;

(b) in any other case, on summary conviction to a fine not exceeding £1,000.

(5) In this section "product summary", in relation to a medicinal product, means the summary of the product characteristics approved by the authority by which the authorisation relating to that product was issued.

(6) The Department may by regulations vary the provisions of this section in its application to any particular case or class of cases.

## 17 Interpretation

(1) Subject to subsections (2) and (3), in this Part, "**advertisement**" includes every form of advertising, whether —

(a) in a publication, or

(b) by the display of any notice, or

(c) by means of any catalogue, price list, letter (whether circular or addressed to a particular person) or other document, or

(d) by words inscribed on any article, or

(e) by means of a photograph, film, sound recording, broadcast or cable programme service, or

(f) in any other way,

and any reference to the issue of an advertisement shall be construed accordingly.

(2) "**Advertisement**" does not include spoken words except words forming part of a sound recording or broadcast or included in a cable programme.

(3) For the purposes of this Part (except section 15(1)(b), (c) or (d)) —

(a) the sale or supply, or offer or exposure for sale or supply, of a medicinal product in a labelled container or package; and

(b) the supply, with a medicinal product of any description, of a leaflet relating solely to medicinal products of that description,

shall not be taken to constitute the issue of an advertisement

(4) In this Part —

"**authorisation**" [Repealed][17]

"**commercially interested party**", in relation to medicinal products of any description, means any person who —

(a) is the holder of an authorisation applicable to medicinal products of that description; or

(b) not being the holder of such an authorisation or licence, is a person who, in the course of a business carried on by him, is engaged or concerned, in relation to medicinal products of that description, in any such activities as are mentioned in section 2(1)(a), (b), (c), (d) or (e); 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;

"**relevant business**" means any business which consists of or includes the sale or supply of medicinal products;

"**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 subsection (2), and any reference to making a representation shall be construed accordingly.

(5) In this section "film", "sound recording", "broadcast", "cable programme", "cable programme service" and related expressions have the same meanings as in the *Copyright Act 1991*.

# PART 4 – ENFORCEMENT

## 18 Enforcement etc

It is the duty of the Department to enforce this Act and any regulations and orders made under it.

## 19 Rights of entry

(1) Subject to the following provisions of this section, any person duly authorised in writing by the Department 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 provision of this Act or of any regulations or order made under this Act; or

(b) generally for the purposes of the performance by the Department of its functions under this Act or under any such regulations or order.

(2) Any person duly authorised in writing by the Department 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 provision of this Act or of any regulations or order made under this Act;

(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) the person so authorised would have a right to enter any premises.

(3) Admission to any premises used only as a private dwelling-house shall not be demanded as of right by virtue of subsections (1) or (2) unless 24 hours' notice of the intended entry has been given to the occupier.

(4) 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 the Department has a right to enter them in accordance with subsections (1) to (3), 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 Department, or any person duly authorised by it, to enter the premises, if need be by force.

(5) Subsection (4) has effect in relation to entering any ship, aircraft, vehicle, stall or place which may be entered under subsection (2) as it has effect in relation to entering any premises as if, in subsection (4) 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.

(6) Any warrant granted under this section shall continue in force for a period of one month.

(7) Any person entering any property by virtue of this section (whether in pursuance of a warrant or not) —

(a) may take with him such other persons and such equipment as may appear to him to be necessary; and

(b) on leaving any such property which he has entered in pursuance of a warrant under subsection (4) 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.

(8) In this section —

"home-going ship" means a ship engaged exclusively in voyages which start and end in the Island and do not involve calling at any place outside the Island;

"property" means any premises, ship, aircraft, vehicle, stall or place.

## 20 Power to inspect, take samples and seize goods and records

(1) For the purpose of ascertaining whether there is or has been a contravention of this Act or of any regulations or order made under it, any person duly authorised in writing by the Department 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 process of manufacture or assembly, for testing the materials after they have been subjected to those processes.

(2) Where, for the purpose specified in subsection (1), 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), 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 records relating to the business which are in his possession or under his control;

(b) to take copies of, or of any entry in, any record produced in pursuance of paragraph (a).

(4) Any person authorised to exercise the power conferred by subsection (3) —

(a) is entitled at any reasonable time to have access to, and inspect and check the operation of, any computer and any associated apparatus

or material which is or has been in used in connection with the records in question; and

(b) may require the person by whom or on whose behalf the computer is or has been used, or any person having charge of or otherwise concerned with the operation of the computer, apparatus or material, to afford him such assistance as he may reasonably require.

(5) Any person so authorised has a right to seize and detain —

(a) 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

(b) any document which he has reasonable cause to believe to be a document which may be required as evidence in proceedings under this Act.

(6) For the purpose of exercising any such right as is specified in subsection (5), the person having that right may, so far as is reasonably necessary in order to secure that this Act and any regulations or order made under it 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.

(7) Where a person seizes any substance or article (including any record) in the exercise of the power conferred by subsection (5), 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.

(8) Notwithstanding anything in subsections (1) to (7), 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 1 have effect with respect to samples obtained on behalf of the Department for the purposes of this Act.

(10) The Department shall by regulations prescribe any matter which under Schedule 1 is to be prescribed.

## 21 Application of sampling procedure to substance or article seized under s 20

(1) The provisions of this section have effect where a person (an "authorised person") seizes a substance or article (other than a record) in the exercise of a right specified in section 20(5).

(2) If any person who, in accordance with section 20(7), 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 21 days after he is informed of the seizure, then, subject to subsection (3), the authorised person 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 person is not required by virtue of subsection (2) 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), an authorised person sets aside a sample, or treats a substance or article as a sample, he shall divide it into 3 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).

(5) Paragraphs 10 to 12 and 15 to 21 of Schedule 1 apply in relation to a sample set aside, or a substance or article treated as a sample, under subsection (2) as if —

(a) any reference to a sampling officer were a reference to an authorised person;

(b) any reference to a sample included a reference to a substance or article treated as a sample; and

(c) in paragraph 19(1) the reference to a substance or article obtained as mentioned in paragraph 1 were a reference to a substance or article of which a sample has been set aside, or which has been treated as a sample, under subsection (2).

## 22 Obstruction etc

(1) Any person who —

(a) intentionally obstructs a person acting in pursuance of this Act and duly authorised so to act by the Department; or

(b) intentionally fails to comply with any requirement properly made to him by a person so acting under section 20 (including that section as modified under section 34(1)); 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,

is guilty of an offence and liable on summary conviction to a fine not exceeding £1,000.

(2) If any person, in giving any such information as is mentioned in subsection (1)(c), makes any statement which he knows to be false, he is guilty of an offence and liable —

(a) on summary conviction, to a fine not exceeding £5,000;

(b) on conviction on information, to custody for a term not exceeding 2 years or to a fine, or to both.

(3) 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 or a civil partner) the spouse or civil partner of that person.[18]

## 23 Analysis of samples in other cases

(1) A person who, not being a person authorised for the purpose by the Department, has purchased a medicinal product may submit a sample of it for analysis to the public analyst who (subject to sub-paragraph (3)) shall as soon as practicable analyse the sample or cause it to be analysed by some other person under his direction.

(2) Paragraphs 2 to 13 and 15 to 18 (except paragraph 15(1)) of Schedule 1 apply in relation a sample submitted under subsection (1) as if any reference to the sampling officer were a reference to the person proposing to submit or submitting the sample.

(3) Where a sample is submitted to the public analyst under subsection (1), he may demand payment in advance of —

(a) the prescribed fee, or

(b) in the case of a sample to be sent under paragraph 15(2) of Schedule 1, such sum as may be agreed;

and, if he demands such payment, he shall not be required to analyse the sample or cause or send it to be analysed until the fee or sum has been paid.

## 24 Liability to forfeiture

(1) For the purposes of section 46 (forfeiture of goods improperly imported) of the *Customs and Excise Management Act 1986* ("the 1986 Act") 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 Department 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 69 of the 1986 Act (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 Department 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 (2) shall be so specified as to consist exclusively of goods appearing to the Department to be goods which are, or normally are, medicinal products.

(4) An order under subsection (1) or (2) shall not have effect unless it is approved by Tynwald.

## 25 Restrictions on disclosure of information

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 19; or

(b) any information obtained by or furnished to him in pursuance of this Act,

unless the disclosure was made in the performance of his duty, he is guilty of an offence and liable —

(i) on summary conviction, to a fine not exceeding £5,000;

(ii) on conviction on information, to custody for a term not exceeding 2 years or to a fine, or to both.

## 26 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 subsection (3), 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), unless, not later than 7 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 sections 7 to 11 and 13 to 16 and any regulations made under any of those sections.

## 27 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 Island 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 —

(a) sections 7(b), 8 and 9, and

(b) regulations under section 2(2).

(3) A warranty shall not be a defence by virtue of this section unless the defendant has, not later than 3 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 an employee 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.

## 28 Offences in relation to warranties and certificates of analysis

(1) If a defendant in any proceedings mentioned in section 27(1) intentionally 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 23, or under paragraph 15(3) of Schedule 1, which relates to a sample of a different substance or article,

he is 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 27, gives to the purchaser a false warranty in writing is 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) Any person guilty of an offence under this section is liable —

(a) on summary conviction, to a fine not exceeding £5,000;

(b) on conviction on information, to custody for a term not exceeding 2 years or to a fine, or to both.

## 29 Offences: general

(1) A complaint may be made in respect of an offence under this Act at any time within 12 months from the time when the cause of complaint arose.

(2) 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 of the following persons —

(a) any director, manager, secretary or other similar officer of the body corporate,

(b) in relation to a body corporate carrying on a retail pharmacy business as mentioned in section 37(1), any person who —

(i) is the superintendent referred to in section 37(1)(a), or

(ii) at any premises where the business is carried on, is the pharmacist referred to in section 37(3) who acts under the direction of the superintendent,[19]

(c) any person who was purporting to act in any capacity mentioned in paragraph (a) or (b),

that person, as well as the body corporate, shall be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

### 30 Presumptions

(1) For the purposes of any proceedings under this Act for an offence consisting of offering a medicinal product for sale, or for sale by retail, in contravention of section 5(2)(a) or 7(b) or regulations under section 2, 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, or for sale by retail, as the case may be.[20]

(2) For the purposes of any proceedings under this Act for an offence consisting of having a medicinal product in one's possession for the purpose of sale or supply, in contravention of section 5(2)(a) or 7(b) or regulations under section 2, 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, 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.[21]

(3) For the purposes of any proceedings under this Act for an offence consisting of the supply of a leaflet with a medicinal product, 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.

## PART 5 – VETERINARY MEDICINAL PRODUCTS AND ANIMAL FEEDING STUFFS

### 31 Veterinary medicinal products

In this Act "**veterinary medicinal product**" means —

(a) any substance or combination of substances presented for treating or preventing disease in animals; or

(b) any substance or combination of substances which may be administered to animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in animals.[22]

## 32 Application of Parts 1 to 4 to veterinary medicinal products

[OJL 311, 28.11.01]

(1) Parts 1 to 4 (including Schedule 1) apply to veterinary medicinal products as they apply to medicinal products, subject to the following modifications.

(2) References to a medicinal product shall be construed as references to a veterinary medicinal product.

(3) In section 1 —

(a) [Repealed][23]

(b) omit subsection (2);

(c) in subsection (3), for the definition of "UK authorisation" substitute —

" "UK authorisation" means —

(a) a marketing authorisation granted in the United Kingdom under the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 (a "UK authorisation")" [SI1994/3142];

(b) a product licence granted in the United Kingdom under section 7 of the UK Act (a "product licence");

(c) a manufacturer's licence granted in the United Kingdom under section 8(2) of the UK Act;

(d) an animal test certificate issued in the United Kingdom under section 32 of the UK Act.";

(d) the power under subsection (4) to amend the definition of "UK authorisation" extends to the definition substituted by paragraph (c).

(3A) In section 5, for subsections (2A) and (2B) substitute —

"(2A) Subsection (2)(a) does not apply to the sale or supply of a veterinary medicinal product for administration to an animal or herd under his care, by a veterinary surgeon or veterinary practitioner who is an appropriate practitioner.

(2B) For the purposes of this section, "appropriate practitioner" means a practitioner referred to in paragraph (b) of the definition of "practitioner" in Schedule 2."[24]

(4) In section 6(3), after paragraph (b) insert "and

(c) the Department of Environment, Food and Agriculture;".[25]

(5) In section 9(4) and (5)(d), for "British Pharmaceutical Codex" substitute "British Veterinary Codex".[26]

## 33 Medicated animal feeding stuffs

(1) The Department may by regulations make provision for controlling, restricting, regulating or prohibiting the following activities —

(a) the incorporation by any person, in the course of a business carried on by him, of a veterinary medicinal product of any description in an animal feeding stuff;

(b) selling, supplying or otherwise placing on the market by any person in the course of a business carried on by him of any animal feeding stuff in which a veterinary medicinal product has been incorporated,

(c) the importation by any person of any animal feeding stuff in which a veterinary medicinal product has been incorporated.

(2) The Department may by regulations —

(a) prohibit or restrict the sale or supply, or the import, of animal feeding stuffs in which veterinary medicinal products of any description, or falling within any class, specified in the order have been incorporated, or

(b) in such manner as may appear to it to be sufficient to identify the feeding stuffs in question, designate particular animal feeding stuffs in which veterinary medicinal products have been incorporated and prohibit or restrict the sale or supply, or the import, of those particular feeding stuffs.

(3) Section 2 applies to any animal feeding stuff in which a veterinary medicinal product of any description has been incorporated as if the references in section 2(2)(a) to (d) (as modified by section 32) to veterinary medicinal products included references to any such animal feeding stuff.

(4) Nothing in subsection (3) affects any requirement imposed by or under the *Fertilisers and Feeding Stuffs Act 1975* with respect to —

(a) marks to be made on a container or package; or

(b) statements to be made in any leaflet supplied, or intended to be supplied, with any material.

(5) Section 6 (as modified by section 32) applies to regulations under this section as it applies to regulations under Part 1.[27]

### 34 Animal feeding stuffs: enforcement

(1) The Department may by regulations provide that any of the provisions of sections 20 to 30 shall apply, with or without prescribed modifications, in relation to animal feeding stuffs as they apply to veterinary medicinal products.

(2) The Department may by regulations make provision as to the manner in which —

(a) samples may be taken by virtue of section 20 (as applied under subsection (1)),

(b) samples may be set aside, or substances or articles may be treated as samples, by virtue of section 21 (as so applied),

(c) samples may be submitted for analysis by virtue of section 23 (as so applied), and

(d) such samples, substances and articles are to be dealt with;

and provision under paragraph (d) may be in substitution for, or by way of modification of or addition to, any of the provisions of Schedule 1.

(3) For the purposes of proceedings for prescribed offences under this Act relating to animal feeding stuffs, the Department may by regulations —

(a) prescribe a method of analysis to be used in analysing samples of animal feeding stuffs in order to determine what quantity or proportion (if any) of a substance or article of a description or class specified in the regulations has been incorporated in them; and

(b) provide that, on production in the proceedings of such evidence as may be so prescribed of the results of an analysis of a sample performed by the method so prescribed, evidence of the results of any analysis of any part of the sample performed by any other method shall not be admissible in those proceedings.[28]

## PART 6 – PHARMACIES

*Conduct of retail pharmacy business*

### 35 Retail pharmacy business

(1) Subject to any regulations under section 39, a person carrying on a retail pharmacy business shall be taken to be a person lawfully conducting such a business if, not being disqualified under section 46 —

(a) that person (or, if the business is carried on by a partnership, each of the partners) is a pharmacist and the conditions specified in section 36 are fulfilled in relation to the business; or

(b) that person is a body corporate and the conditions specified in section 37 are fulfilled in relation to the business; or

(c) that person is a representative of a pharmacist (as defined by section 38(4)) and the conditions specified in section 38(2) are fulfilled in relation to him and in relation to the business and the period applicable in accordance with section 38(3) has not expired.

(2) For the purposes of the application of this Part 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 also carried on elsewhere or not,

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

(3) In this section and sections 36 to 38 and 43 references to medicinal products include references to veterinary medicinal products.

## 36 Business carried on by individual pharmacist or firm

(1) The conditions referred to in section 35(1)(a) are the conditions set out in this section and each condition must be satisfied with respect to each of the premises at which the retail pharmacy business is carried on and medicinal products, other than medicinal products on general sale, are sold by retail.

(2) The responsible pharmacist must be in charge of the business carried on at the premises referred to in subsection (1), so far as concerns —

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

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

(3) The responsible pharmacist must be —

(a) the person carrying on the business;

(b) one of the partners where the business is carried on by a partnership; or

(c) another pharmacist.

(4) A notice must be conspicuously displayed at the premises stating —

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

(b) the number of the pharmacist's certificate of registration; and

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

(5) The responsible pharmacist must 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 medicinal products on general sale or not); and

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

(6) The responsible pharmacist must not be absent from the premises unless —

(a) the maximum period that the premises will be without a responsible pharmacist is no more than two hours during the pharmacy's business hours; and

(b) arrangements have been put in place to ensure that, where it is reasonably practicable for the responsible pharmacist to be contactable throughout the period of absence, the responsible pharmacist or another pharmacist can —

(i) be contacted by other pharmacy staff throughout the period of absence; and

(ii) return to the premises with reasonable promptness if, in the opinion of the responsible pharmacist, this is necessary to secure the safe and effective running of the pharmacy business.

(7) For the purposes of —

(a) subsection (6)(a), if there is more than one responsible pharmacist during the pharmacy's business hours, the maximum period in that subsection relates to the total period of absence for all of them; and

(b) subsection (6)(b), where it is not reasonably practicable to put in place the arrangements specified in that subsection, arrangements must ensure that another pharmacist is both available and contactable to provide advice to other pharmacy staff.

(8) The retail sale of medicinal products on general sale may continue during a period when the responsible pharmacist is absent from the premises.

(9) The responsible pharmacist must establish (if they are not already established), maintain, keep under review and produce in accordance with subsection (10) procedures designed to secure the safe and effective running of the business.

(10) Pharmacy procedures must —

(a) cover the matters specified in subsection (11);

(b) be recorded —

(i) in writing;

(ii) in electronic form; or

(iii) in both forms;

(c) be available at the premises for inspection by —

(i) the person carrying on the pharmacy business;

(ii) the superintendent, if any;

(iii) the responsible pharmacist; and

(iv) pharmacy staff; and

(d) be reviewed regularly.

(11) The matters which must be covered by pharmacy procedures are —

(a) the arrangements to secure that medicinal products are —

(i) ordered;

(ii) stored;

(iii) prepared;

(iv) sold by retail;

(v) supplied in circumstances corresponding to retail sale;

(vi) delivered outside the pharmacy; and

(vii) disposed of,

in a safe and effective manner;

(b) the circumstances in which a member of pharmacy staff who is not a pharmacist may give advice about medicinal products;

(c) the identification of members of pharmacy staff who are, in the view of the responsible pharmacist, competent to perform certain tasks relating to the pharmacy business;

(d) the keeping of records about the arrangements mentioned in paragraph (a);

(e) the arrangements which are to apply during the absence of the responsible pharmacist from the premises;

(f) the steps to be taken when there is a change of responsible pharmacist at the premises;

(g) the procedure which is to be followed if a complaint is made about the pharmacy business;

(h) the procedure which is to be followed if an incident occurs which may indicate that the pharmacy business is not running in a safe and effective manner; and

(i) the manner in which changes to the pharmacy procedures are to be notified to pharmacy staff.

(12) The responsible pharmacist must make a record and such record must —

(a) include the particulars set out in subsection (13);

(b) be kept —

(i) in writing;

(ii) in electronic form; or

(iii) in both forms;

(c) be available at the premises for inspection by —

(i) the person carrying on the pharmacy business;

(ii) the superintendent, if any;

(iii) the responsible pharmacist; and

(iv) pharmacy staff.

(13) The particulars that must be included in the pharmacy record are —

(a) the responsible pharmacist's name;

(b) the number of the responsible pharmacist's certificate of registration;

(c) the date and time at which the responsible pharmacist became the responsible pharmacist;

(d) the date and time at which the responsible pharmacist ceased to be the responsible pharmacist; and

(e) in relation to any absence of the responsible pharmacist from the premises on a day on which they were the responsible pharmacist —

(i) the date of the absence;

(ii) the time at which the absence commenced; and

(iii) the time at which the responsible pharmacist returned to the premises.

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

(a) the record is properly maintained; and

(b) the record is preserved for a period of not less than five years commencing on —

(i) in the case of a record in electronic form, the day on which it is created;

(ii) in the case of a written record, the last day to which the record relates.

(15) If a person fails to comply with any requirements as to absence from the premises contained in subsection (6), that person is not to be considered, while the failure continues, as being in charge of the business carried on at or from those premises.[29]

## 37 Bodies corporate

(1) The conditions referred to in section 35(1)(b) are that —

(a) there is a superintendent in relation to the retail pharmacy business in respect of whom the requirements specified in subsection (2) are fulfilled; and

(b) subsections (3) and (4) are both satisfied as respects each of the premises at which the business is carried on and medicinal products, other than medicinal products on general sale, are sold by retail.[30]

(2) The requirements referred to in subsection (1) in relation to a superintendent are that —

(a) the superintendent 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.

(3) This subsection is satisfied if a responsible pharmacist who satisfies the requirement of subsection (5) is in charge of the business carried on at the premises mentioned in subsection (1)(b), so far as concerns —

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

(b) the supply at those premises of such products in circumstances corresponding to retail sale.[31]

(4) 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 the pharmacist's certificate of registration; and

(c) the fact that the pharmacist is for the time being in charge of the business carried on at those premises.[32]

(5) The responsible pharmacist must be —

(a) the superintendent mentioned in subsection (1)(a); or

(b) a manager or assistant subject to the directions of the superintendent and who is a pharmacist.[33]

(6) The responsible pharmacist must comply with the requirements of section 36(5) to (14).[34]

(7) For the purposes of this section, where the responsible pharmacist does not comply with the requirements referred to in subsection (6) then section 36(15) may apply wherever relevant.[35]

(8) If a person who has managed a 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 that fact within the period of

28 days beginning with the day on which the person ceases to manage the business.[36]

## 38 Representative of pharmacist in case of death or disability

(1) This section has 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

(c) a receiver is appointed for him under Part 7 of the *Mental Health Act 1998*,

and a representative of his thereafter carries on his business.

(2) The conditions referred to in section 35(1)(c) are that —

(a) 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) subsections (2A) and (2B) are both satisfied as respects each of the premises at which the business is carried on and medicinal products, other than medicinal products on general sale, are sold by retail.[37]

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

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

(b) the supply at those premises of such products in circumstances corresponding to retail sale.[38]

(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 the pharmacist's certificate of registration; and

(c) the fact that the pharmacist is for the time being in charge of the business carried on at or from those premises.[39]

(2C) The responsible pharmacist must comply with the requirements of section 36(5)-(14).[40]

(2D) For the purposes of this section, where the responsible pharmacist does not comply with the requirements referred to in subsection (2C) then section 36(15) may apply wherever relevant.[41]

(3) The period referred to in section 35(1)(c) is —

(a) in the case of the death of a pharmacist, 5 years from the date of his death;

(b) in the case of the bankruptcy of the estate of a pharmacist, 3 years from the date on which he is adjudged bankrupt;

(c) in the case of a composition or scheme or deed of arrangement, 3 years from the date on which the trustee appointed under it becomes entitled to carry on the business; and

(d) in a case falling within subsection (1)(c), 3 years from the date of the appointment of the receiver, or

(e) in any case, such longer period as, on the application of the representative, the Department 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 —

(i) means his executor or administrator and

(ii) in respect of a period of 3 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 persons beneficially interested in his estate;

(b) in a case within subsection (1)(b), means the trustee in bankruptcy or any trustee appointed under the composition, scheme or deed of arrangement; and

(c) in a case within subsection (1)(c), means the receiver.

## 39 Power to extend or modify conditions

(1) The Department may by regulations add to, revoke or vary any of the provisions of sections 36 to 38, so as either —

(a) to modify, or provide new conditions in substitution for, the conditions referred to in paragraph (a), (b) or (c) of section 35(1); 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 regulations under subsection (1) may be made either generally or in relation to any particular circumstances specified in the regulations.

(3) Regulations under subsection (1) may direct that section 35(1) or (2) shall have effect subject to such exceptions or modifications as appear to the Department to be necessary or expedient in consequence of the provision made by the regulations in accordance with subsection (1).

(4) Where regulations under subsection (1) are for the time being in force, any reference to section 35 in any other enactment shall be construed as a reference to that section as modified by the regulations.

*Registration of pharmacies*

## 40 Registration of premises

(1) The registrar shall —

(a) keep a register for the purposes of this section ("the register"), and

(b) subject to the following provisions of this section, on payment of the prescribed fee 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 —

(a) be made in the prescribed manner,

(b) specify the premises to which the application relates, and shall

(c) contain such other particulars as may be prescribed.

(3) 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 that either —

(a) at the time of the application, the applicant is a person lawfully conducting a retail pharmacy business; or

(b) 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.

## 41 Registration: supplemental

(1) Where any premises have been entered in the register, then, in respect of each year subsequent to the year in which the premises were so entered, a further fee (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 fails to pay a retention fee in respect of those premises within 2 months from the date on which the demand is made, the Department 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 Department 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 Department 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 40, 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 3 months from the date of the death; and

(b) in any other case, shall become void at the end of the period of 28 days from the date on which the change occurs.

(4) Where the registration of any premises under section 40 in respect of a business becomes void by virtue of subsection (3), 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.

(5) A document purporting to be a certificate signed by the registrar and stating that, on a specified date, specified premises 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.

(6) In this section "year" means a period of 12 months beginning on such date as the Department may from time to time determine.

## 42 Appeals relating to registration

(1) Any person who is aggrieved by the refusal of the registrar of an application under section 40 may within 14 days of the notification of it to him appeal to the High Bailiff.

(2) The High Bailiff may uphold an appeal under this section if he considers that the registrar —

(a) erred in law; or

(b) based his decision on any incorrect material fact.

(3) Where the High Bailiff upholds an appeal under this section, the registrar shall give effect to his order, and in particular shall make any necessary entry in the register.

## 43 Annual return of premises

(1) Every person who carries on a retail pharmacy business shall, in the month of January in each year, send to the registrar —

(a) a list of all premises at which his business, so far as it consists of the retail sale of medicinal products, is carried on; and

(b) [Repealed][42]

(2) Any person who contravenes subsection (1) is guilty of an offence and liable on summary conviction to a fine not exceeding £1,000.

*Use of certain titles, descriptions and emblems*

## 44 Restrictions on use of titles, descriptions and emblems

(1) No person shall —

(a) take or use any of the following titles —

chemist and druggist,

druggist,

dispensing chemist, or

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 subsection (2) are fulfilled.

(2) Those conditions are —

(a) in the case of an individual, that —

(i) he is a person lawfully conducting a retail pharmacy business (either alone or as a member of a partnership), and

(ii) 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;

(b) in the case of a body corporate, that —

(i) the body is a person lawfully conducting a retail pharmacy business,

(ii) 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

(iii) that the pharmacist who, in relation to that business, is such a superintendent as is referred to in section 37(1) is a member of the board of the body corporate.

(3) 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.

(4) No person who is not a pharmacist shall take or use any of the following titles —

pharmaceutical chemist,

pharmaceutist,

pharmacist,

member of the Royal Pharmaceutical Society, and

fellow of the Royal Pharmaceutical Society.

(5) Without prejudice to subsection (4), no person shall take or use any of those titles 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.

(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 or veterinary 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 subsection (8), 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 —

(a) the person carrying on the business (where that person is not a body corporate) is a pharmacist, and

(b) any other person who is in charge of the business at those premises (so far as concerns the retail sale of medicinal products or

veterinary medicinal products or the supply of such products in circumstances corresponding to retail sale) is also a pharmacist.[43]

(8) Where a person is lawfully conducting a retail pharmacy business as being a representative of a pharmacist in the circumstances specified in section 35(1)(c), subsections (4) to (7) 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.

(9) Any person who contravenes this section is guilty of an offence and liable on summary conviction to a fine not exceeding £1,000.

## 45 Modification etc of restrictions under s 44

(1) The Department may by regulations provide that any of the restrictions imposed by section 44 shall cease to have effect, or shall have effect subject to such exceptions as may be specified in the regulations.

(2) Without prejudice to subsection (1), the Department may by regulations impose (in addition to the restrictions under section 44) such further restrictions or other requirements with respect to the use of titles, descriptions and emblems as may be specified in the regulations.

(3) Any person who contravenes regulations under subsection (2) is guilty of an offence and liable on summary conviction to a fine not exceeding £1,000.

*Disqualification, and removal of premises from register*

## 46 Power of Department 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 any of the relevant Acts; or

(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 Department 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, the Department, after inquiring into the case, may direct that the body corporate shall be disqualified for the purposes of this Part.

(2) In any case falling within subsection (1) —

(a) if the Department gives a direction under that subsection, it 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 Department does not give a direction under subsection (1), it may, if it thinks 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) or (2)(a) or (b) may, if the Department thinks 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 subsection (2)(a) or (b).

(4) Where, in a case mentioned in section 38(1), a representative, or a person employed by a representative in the business there referred to —

(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 Department renders him, or would if he were a pharmacist render him, unfit to be a pharmacist, the Department, after inquiring into the case, may direct that the representative shall be disqualified for the purposes of this Part.

(5) In this section and in section 47 "**the relevant Acts**" means —

(a) the *Misuse of Drugs Act 1976*;

(b) this Act; and

(c) any enactment in force in any part of the British Islands (other than the Island) corresponding to any of those enactments.

## 47 Grounds for disqualification in certain cases

(1) The Department shall not give a direction under section 46(1), in a case falling within section 46(1)(b), and shall not give a direction under section 46(4), unless —

(a) one or more of the facts specified in subsection (2) are proved to the satisfaction of the Department; and

(b) the Department is of the opinion, having regard to those facts, that the board of the body corporate or the representative, as the case may be, is to be regarded as responsible for the offence or misconduct in question.

(2) The facts referred to in subsection (1)(a) are —

(a) that the offence or misconduct 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 12 months before the date on which the offence or misconduct in question occurred, been guilty of a similar offence or similar misconduct and that the board had, or with the exercise of reasonable care would have had, knowledge of that previous offence or misconduct;

(c) that, in the case of the representative, he or a person employed by him had, at some time within 12 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 or misconduct in question is a continuing offence or 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.

## 48 Appeal against disqualification etc

(1) A direction under section 46 shall not take effect —

(a) until the end of the period of 3 months from the date on which notice of the direction is given to the body corporate or other person to whom it relates, and

(b) if an appeal against the direction is brought under this section, until that appeal has been determined or withdrawn.

(2) 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 3 months specified in subsection (1)(a), appeal against the direction to the High Court.

(3) The Department 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 Department shall be deemed to be a respondent to the appeal whether it appears on the hearing of the appeal or not.

(4) On any such appeal, the Court may give such directions in the matter as appear to it to be appropriate; and the Department shall comply with any such directions and (where appropriate) the registrar shall make such alterations in the register as are necessary to give effect to them.

(5) No appeal shall lie from any decision of the High Court under this section.

### 49 Revocation of disqualification

(1) The Department may revoke a direction under section 46, either on the application of the person to whom it relates or without any application.

(2) If, on an application to the Department to revoke such a direction, the Department refuses to revoke it, the applicant, at any time before the end of the period of 3 months from the date on which notice of the refusal is given to him, may appeal to the High Court against the refusal.

(3) Section 48(3) to (5) has effect in relation to any appeal under this section as it has effect in relation to appeals under section 48.

## PART 7 – SUPPLEMENTAL

### 50 Extension of application of Act

(1) The Department may by order —

(a) specify any description or class of articles or substances appearing to it to be articles or substances which are not medicinal products or veterinary medicinal products but are manufactured, sold, supplied, imported or exported for use wholly or partly for a medicinal purpose, and

(b) direct that, subject to such exceptions and modifications as may be specified in the order, such provisions of this Act 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 or veterinary medicinal products, as the case may be.

(2) The Department may by order —

(a) specify any substance appearing to the Department to be a substance which is not itself a medicinal product or veterinary medicinal product but —

(i) is used as an ingredient in the manufacture of medicinal products or veterinary medicinal products; or

(ii) if used without proper safeguards, is capable of causing danger to the health of the community, or of causing danger to the health of animals generally or of one or more species of animals, and

(b) direct that, subject to such exceptions and modifications as may be specified in the order, such provisions of this Act 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 or veterinary medicinal products, as the case may be.

(3) The power conferred by subsection (2) may be exercised in relation to a class of substances if it appears to the Department that the conditions specified in subsection (2)(a)(i) or (ii) are fulfilled in relation to all substances falling within that class.

(4) An order under this section shall not have effect unless it is approved by Tynwald.

## 51 References to specified publications

(1) In this section "specified publication" means —

(a) the European Pharmacopoeia;

(b) the British Pharmacopoeia;

(c) the British Pharmaceutical Codex;

(d) the British Veterinary Codex;

(e) the British National Formulary;

(f) the Dental Practitioners' Formulary;

(g) any compendium prepared and published under section 99(3) and (6) of the UK Act;

(h) any list of names prepared and published under section 100 of the UK Act.

(2) Where any authorisation, licence or certificate 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) Subsection (4) applies where —

(a) under any statutory provision other than this Act (whenever made) there is power to make any public document, list or other instrument which is to have effect by virtue of, or for the purposes of, that provision, and

(b) an instrument made in 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 subsection (4), be made so as to refer to the current edition of a specified publication as in force at a subsequent time;

unless, in the case of a statutory provision made after 1985, it otherwise expressly provides.

(4) The power to make an instrument referred to in subsection (3) may 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.

(5) In this section —

(a) any reference to the current edition of a specified publication as in force at any particular time is a reference to the edition of that publication in force at that time together with any amendments, additions or deletions made to it up to that time; and

(b) any reference to making an instrument in the exercise of a power conferred by a statutory provision includes a reference to issuing, approving or varying such an instrument.

## 52 Regulations

(1) The Department may by regulations prescribe anything which is to be prescribed under or for purposes of this Act.

(2) Regulations under this Act shall not have effect unless they are approved by Tynwald.

(3) Regulations under this Act —

(a) may for the purposes of the regulations apply any UK medicines legislation to the Island as part of the law of the Island, subject to such exceptions, adaptations and modifications as may be specified in the regulations; and

(b) may so apply any order or regulations made under the UK Act which may from time to time be in force in the United Kingdom (that is, any such order or regulations made after as well as before the making of the regulations under this Act).

(4) Regulations under this Act may include provision repealing or amending any provision of an enactment (other than this Act) which appears to the Department to be inconsistent with, or to be unnecessary or to require modification in consequence of, the order or regulations or any UK medicines legislation thereby applied to the Island.

(5) Where regulations under this Act make provision —

(a) under subsection (3), or

(b) corresponding to any UK medicines legislation,

that provision may be made retrospective to such date as may be specified in the regulations, not being earlier than the date from which the relevant UK medicines legislation had effect in England and Wales.

(6) A statement contained in regulations under this Act that any provision of them corresponds to any UK medicines legislation shall be conclusive evidence of that fact.

## 53 "Retail sale" and related expressions

(1) 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 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.

(2) 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 it for such a purpose as is mentioned in subsection (1).

(3) For the purposes of this section the provision of services by or on behalf of the Department under the *National Health Service Act 2001* shall be treated as the carrying on of a business by that Department.

## 54 Interpretation: general

Schedule 2 has effect for the purpose of defining certain expressions in this Act.

## 55 Transitional provisions, amendments and repeals

(1) The following provisions, as they have effect immediately before the coming into operation of section 2, shall continue to have effect as if contained in regulations under Part 1 (or, where appropriate, that Part as modified by section 32), and may be amended or revoked accordingly —

(a) sections 7 to 15 of the *Medicines Act 1976*, and any order made under any of those sections;

(b) so far as they relate to wholesale licences, sections 18 to 24, 28 to 30, 44 and 47 of that Act, and any order made under any of those sections;

(c) section 34, 45 and 46 of that Act.[44]

(2) An order under section 56(2) may make such further transitional provision as appears to the Department to be necessary or expedient.

(3) The enactments specified in Schedule 3 are amended in accordance with that Schedule.

(4) The enactments specified in Schedule 4 are repealed to the extent specified in column 3 of that Schedule.

## 56 Short title and commencement

(1) This Act may be cited as the Medicines Act 2003.

(2) This Act shall come into operation on such day or days as the Department may by order appoint.[45]

# SCHEDULE 1

# SAMPLING

Section 20(9)

*Introductory*

1. This Schedule has effect where a person authorised for the purpose by the Department (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 under it; or

(b) otherwise for any purpose connected with the performance by the Department of its 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 20.

*Division of sample*

2. The sampling officer shall forthwith divide the sample into 3 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 Island, 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 Island 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 paragraphs 3 to 5, 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 paragraphs 3 to 6, 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 paragraphs 3 to 7, 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 paragraphs 3 to 8, 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, 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 containers 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 3 lots without opening them.

12. Part 4, Division 5 of the *Interpretation Act 2015* (service of documents) applies to supplying any part of a sample in pursuance of the preceding paragraphs of this Schedule as it applies to the service of a document.[46]

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 paragraphs 1 to 12, 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 Island are stated on the 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 paragraph (1) shall be served before the end of the period of 3 days beginning with the day on which the sample was obtained.

*Analysis or other examination of sample*

15. (1) If the sampling officer decides to submit the sample for analysis, he shall submit it to the public analyst, who (subject to sub-paragraph (2)) shall as soon as practicable analyse the sample or cause it to be analysed by some other person under his direction.

(2) If —

(a) the office of public analyst is vacant and no provision has been made under sections 77 (acting appointments: general provisions), 78 (acting appointments: directions about appointor) and 79 (power of appointment includes certain incidental powers) of the *Interpretation Act 2015* for some other person to exercise his functions, or[47]

(b) the public analyst determines that he is for any reason unable to perform an effective analysis,

the sampling officer or the public analyst, as the case may be, shall send the sample to a public analyst in the United Kingdom with the request that, on payment to him of such sum as may be agreed, he shall analyse it or cause it to be analysed by some other person under his direction, and issue to the sampling officer a certificate under sub-paragraph (3).

(3) A public analyst who has analysed a sample under this paragraph shall issue to the sampling officer a certificate specifying the result of the analysis.

(4) Where a sample taken or purchased by a sampling officer has been analysed by a public analyst, any person to whom a part of the sample was given in accordance with paragraphs 2 to 8 is entitled, on paying the prescribed fee to the Department, to be supplied with a copy of the certificate given by the analyst under sub-paragraph (3).

(5) A certificate under sub-paragraph (3) shall be in a prescribed form and signed by the public analyst who issues it.

*Provisions as to evidence*

16. 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 15 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.

17. 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.

18. (1) If, in any such proceedings before a court of summary jurisdiction, 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 3 clear days before the day on which the summons is returnable.

(2) If sub-paragraph (1) is not complied with, the court may, if it thinks fit, adjourn the hearing on such terms as it thinks proper.

*Analysis under direction of court*

19. (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, the part of the sample retained in pursuance of paragraph 10(a) 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 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 sub-paragraph (1), 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 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.

20. The costs of any analysis or examination under paragraph 19 shall be paid by the prosecutor or the defendant, as the court may order.

*Power to modify sampling provisions*

21. The Department may by regulations provide that, in relation to substances or articles of any prescribed description, paragraphs 1 to 20 shall have effect subject to such exceptions and modifications as may be prescribed.

Payment for sample taken under compulsory powers

22. (1) Where a sampling officer takes a sample in the exercise of any power conferred by section 20, 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, 7 or 8, as the case may be, to be supplied.

(2) In default of agreement between the sampling officer and the person mentioned in sub-paragraph (1), 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 High Bailiff.

*Application of section 8 to samples*

23. Where a medicinal product is taken as a sample by a sampling officer in the exercise of any power conferred by section 20, section 8(1) to (4) applies 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, section 8(1) to (4) shall so apply as if, in section 8(1), for "demanded by the purchaser" there were substituted "specified in the prescription".

# SCHEDULE 2

# INTERPRETATION

Section 54

| **Expression** | **Meaning** |
|---|---|
| **administering**[48] | means administering to a human being, or as the case may be, an animal, —<br>(a) orally, by injection, or by introduction into the body in any other way, or<br>(b) by external application whether or not by direct application to the body,<br>and, save where expressly provided, any reference in this Act to administering anything is to administering it in its existing state or after it has been dissolved or dispersed in, or diluted or mixed with, a substance used as a vehicle |
| **analysis** | includes micro-biological assay but no other form of biological assay, and "**analyse**" has a corresponding meaning |
| **animal** | includes any bird, fish or reptile |

| Expression | Meaning |
|---|---|
| **assemble (in relation to a medicinal product or veterinary medicinal product)** | means enclosing the product (with or without other 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 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 |
| **authorisation**[49] | means a UK authorisation, an EU authorisation or any other authorisation that has effect in the Island pursuant to regulations made under section 2 or 52 |
| **board (in relation to a body corporate)** | means the body of persons controlling the body corporate, by whatever name called |
| **business** | includes a professional practice and any activity carried on by a body or persons, whether corporate or unincorporated |
| **certificate of registration** | means a certificate of registration under the Pharmacy Act 1954 (an Act of Parliament) or any Act of Parliament replacing that Act |
| **Community authorisation**[50] | [Repealed] |
| **EU instrument**[51] | has the meaning given in the *Interpretation Act 2015* |
| **composition (in relation to a medicinal product)** | means the ingredients of which the product 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 or veterinary medicinal product)** | means the bottle, jar, box, packet or other receptacle which contains or is to contain the product, not being a capsule, cachet or other article in which it 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 registered dentist within the meaning of the *Dental Act 1985* |
| **Department** | means the Department of Health and Social Care[52] |
| **disease** | includes any injury, ailment or adverse condition, whether of body or mind |
| **doctor** | means a registered medical practitioner[53] |
| **EC code** | means Directive 2001/83/EC on the Community code relating to medicinal products for human use |
| **EC Regulation**[54] | means Regulation (EC) 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency |
| **EC veterinary code** | means Directive 2001/82/EC on the Community code relating to veterinary medicinal products |

| Expression | Meaning |
|---|---|
| **health centre** | means a health centre maintained under section 15 of the *National Health Service Act 2001* |
| **hospital** | includes a clinic, nursing home or similar institution |
| **ingredient (in relation to the manufacturer or preparation of a substance)** | includes anything which is the sole active ingredient of that substance as manufactured or prepared |
| **label (in relation to a container or package of a medicinal product or veterinary medicinal product)** | means a notice describing or otherwise relating to the contents and affixed to or otherwise displayed on the container or package, and "**labelling**" has a corresponding meaning |
| **manufacture (in relation to a medicinal product or veterinary 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 and does not include the incorporation of the product in any animal feeding stuff |
| **medicinal product** | has the meaning given by section 1(2) |
| **medicinal product (or veterinary medicinal product) on general sale** | medicinal means a medicinal product (or veterinary medicinal product) to which section 4 applies |
| **offence under this Act** | includes an offence under any regulations or order made under this Act |
| **package (in relation to any medicinal products or veterinary 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 |
| **pharmacist** | means a person registered in the register of pharmaceutical chemists maintained under section 2(1) of the Pharmacy Act 1954 (an Act of Parliament) |

| **Expression** | **Meaning** |
|---|---|
| **practitioner** | means —<br>(a) in relation to medicinal products —<br>(i) a doctor,<br>(ii) a dentist,<br>(iii) a registered nurse holding prescribed qualifications or fulfilling prescribed conditions,<br>(iv) a registered midwife holding prescribed qualifications or fulfilling prescribed conditions, or (v) any other person holding prescribed qualifications or fulfilling prescribed conditions;<br>(b) in relation to veterinary medicinal products —<br>(i) a veterinary surgeon,<br>(ii) [Repealed] [or<br>[Subpara (ii) repealed by *Veterinary Surgeons Act 2005* Schs 2 and 3.]<br>(iii) any other person holding prescribed qualifications or fulfilling prescribed conditions |
| **prescribed** | means prescribed by regulations under this Act |
| **registered** | [Repealed][55] |
| **registered pharmacy** | means premises for the time being entered in the register required to be kept under section 40 |
| **registrar (in Part 6)** | means the person appointed by the Department to be registrar for the purposes of Part 6 |
| **requirement** | includes a restriction |
| **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 general sale (whether medicinal products on general sale are sold in the course of that business or not) |
| **retail sale (or selling by retail)** | has the meaning given by section 53 |
| **substance** | means any natural or artificial substance, whether in solid or liquid form or in the form of a gas or vapour |
| **supply in circumstances corresponding to retail sale** | has the meaning given by section 53 |
| **treat (in relation to disease)** | includes doing or providing anything for alleviating the effects of the disease, whether it is done or provided by way of cure or not, and "**treatment**" has a corresponding meaning |
| **UK Act** | means the Medicines Act 1968 (an Act of Parliament) |
| **UK authorisation** | subject to section 32, has the meaning given by section 1(3) |

| Expression | Meaning |
|---|---|
| **UK medicines legislation** | means, —<br>(a) any provision of the UK Act,<br>(b) any provision of any Act of Parliament, or of any statutory instrument, amending, varying, modifying or replacing the UK Act, whether directly or indirectly;<br>(c) any statutory instrument made under the UK Act or any Act referred to in paragraph (b); or<br>(d) any Parliamentary enactment or any EU-derived domestic legislation or retained direct EU legislation (within the meaning given to both terms by the European Union (Withdrawal) Act 2018 (of Parliament)) giving effect to any provision of —<br>(i) the EC Code,<br>(ii) the EC veterinary code,<br>(iii) the EC Regulation, or<br>(iv) any EU instrument from time to time amending or replacing any of the instruments mentioned in sub-paragraphs (i), (ii) and (iii).[56] |
| **veterinary medicinal product** | has the meaning given by section 31 |
| **veterinary practitioner** | [Repealed][57] |
| **veterinary surgeon** | means a person registered in the register of veterinary surgeons kept under section 2 of the said Act of 1966 |

# SCHEDULE 3

# AMENDMENT OF ENACTMENTS

Section 55(3)

[Sch 3 amended by Veterinary Surgeons Act 2005 Schs 2 and 3, and amends the following Acts —

Cancer Act 1942 q.v.

Consumer Protection (Trade Descriptions) Act 1970 q.v.

Misuse of Drugs Act 1976 q.v.

Poisons Act 1979 q.v.

Local Government (Miscellaneous Provisions) Act 1984 q.v.

Consumer Protection Act 1991 q.v.

Licensing Act 1995 q.v.

Value Added Tax Act 1996 q.v.

Food Act 1996 q.v.

Cruelty to Animals Act 1997 q.v.

Shops Act 2000 q.v.

National Health Service Act 2001 q.v.]

## SCHEDULE 4

## ENACTMENTS REPEALED

Section 55(4)

[Sch 4 repeals the following Acts in part —

Medicines Act 1976

Poisons Act 1979

Medical Act 1985

Treasury Act 1985

Dental Act 1985

Customs and Excise Management Act 1986

Statute Law Revision Act 1989

Copyright Act 1991

Statute Law Revision Act 1992

National Health Service Act 2001.]

# ADDENDUM

**Editorial Note**: The following provisions of the *Medicines Act 1976*, as they had effect immediately before the coming into operation of section 2 of this Act on 1 November 2004, shall continue to have effect as if contained in regulations under Part 1 (or, where appropriate, that Part as modified by section 32), and may be amended or revoked accordingly.
The provisions have been reproduced here for the convenience of users.

## 7 General provisions as to dealing with medicinal products

[P1968/67/7]

(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) the provisions of this Part of this Act relating to clinical trials and medicinal tests on animals; 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 or cause to be imported any medicinal product except in accordance with a product licence.

(4) In relation to an imported medicinal product, subsection (2) above 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) above 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 that product, or

(b) if that product is a proprietary medicinal product or a ready-made veterinary drug, is responsible for the placing of the product on the market in the Island.

(6) For the purposes of subsection (5) above, 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 paragraph (a) above.

(7) Nothing in this section shall prohibit the grant of a product licence to a person, who is not in the Island, for the purpose of enabling him to cause a medicinal product to be imported into the Island.

(8) In subsection (5) of this section —

(a) "proprietary medicinal product" means a ready-prepared medicinal product placed on the market in the Island under a special name and in a special pack; and for the purposes of this definition "medicinal product" does not include: —

(i) vaccines, toxins and serums,

(ii) medicinal products based on human blood or blood constituents or radioactive isotopes,

(iii) homeopathic veterinary drugs, or

(iv) additives for animal feeding stuffs to which the provisions of Council Directive 70/524/EEC apply.

(b) "ready-made veterinary drug" means a ready-prepared veterinary drug placed on the market in the Island in a pharmaceutical form in which it may be used without further processing, not being a drug placed on the market under a special name and in a special pack; and for the purposes of this definition "veterinary drug" does not include: —

(i) vaccines, toxins or serums;

(ii) veterinary drugs based on radioactive isotopes,

(iii) veterinary drugs specially prepared for administration by a veterinary surgeon or veterinary practitioner to a particular animal or herd which is under his care;

(iv) homeopathic veterinary drugs;

(v) additives for animal feeding stuffs to which the provisions of Council Directive 70/524/EEC apply.

## 8 Provisions as to manufacture and wholesale dealing

[P1968/67/8]

(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) to (c) of subsection (1) of that section.

(2) No person shall, in the course of a business carried on by him, manufacture or assemble 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").

(3) 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 ready-made veterinary drug which has been imported, but was not consigned from a Member State,

except in accordance with a licence granted for the purposes of this subsection (in this Act referred to as a "wholesale dealer's licence").

(4) Subsection (8) of section 7 of this Act shall apply for the purposes of subsection (3) of this section as it applies for the purposes of subsection (5) of that section.

## 9 Exemptions for doctors, dentists, veterinary surgeons and veterinary practitioners

[P1968/67/9]

(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) Subject to subsection (3) below, the restrictions imposed by sections 7 and 8 of this Act do not apply to anything done by a veterinary surgeon or veterinary practitioner which —

(a) relates to a medicinal product specially prepared for administration to a particular animal or herd which is under his care, 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 a person having the possession or control of that animal or herd; or

(b) relates to a medicinal product specially prepared at the request of another veterinary surgeon or veterinary practitioner for administration to a particular animal or herd which is under the care of that other veterinary surgeon or veterinary practitioner, and consists of manufacturing or assembling, or procuring the 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 veterinary surgeon or veterinary practitioner or to a person having the possession or control of that animal or herd.

(3) Subsection (2) above shall not have effect so as to exempt from the restrictions imposed by sections 7 and 8 of this Act anything done by a veterinary surgeon or veterinary practitioner —

(a) in relation to a vaccine specially prepared for administration to poultry; or

(b) in relation to any other vaccine, unless the vaccine is specially prepared for administration to the animal from which it is derived; or

(c) in relation to plasma or a serum, unless the plasma or serum is specially prepared for administration to one or more animals in the herd from which it is derived.

## 10 Exemptions for pharmacists

[P1968/67/10; SI1971/1445/3]

(1) Subject to subsection (2) below, 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 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, but, 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 by a practitioner, or of procuring the assembly of a medicinal product.

(2) The exemption conferred by subsection (1) above does not apply to a vaccine specially prepared for administration to poultry, and does not apply to any other vaccine or any plasma or serum prepared or dispensed for administration to an animal or herd unless —

(a) in the case of a vaccine, it is specially prepared for administration to the animal from which it is derived; or

(b) in the case of plasma or a serum, it is specially prepared for administration to one or more animals in the herd from which it is derived,

and (in either case) it is so prepared in accordance with a prescription given by a veterinary surgeon or veterinary practitioner.

(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; or

(b) the product, not being a vaccine, plasma or serum, is prepared or dispensed for administration to an animal or herd which is in the possession or under the control of that person.

(4) Without prejudice to subsections (1) to (3) above, 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 medicinal products with a view to dispensing them as mentioned in subsection (1)(a) or (3) above or in paragraph (a) above, so long as 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) above.

(5) Without prejudice to subsections (1) to (4) above, 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;

(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 subsections (1) to (5) above, 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.

(7) Without prejudice to subsections (1) to (6) above, the restrictions imposed by section 8(3) 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.

(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.

## 11 Exemption for nurses and midwives

[P1968/67/11]

(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 nurse or as a registered midwife.

(2) In this section, "registered nurse" and "registered midwife" have the same meanings respectively as in the *Nurses and Midwives Act 1947*.

## 12 Exemptions in respect of herbal remedies

[P1968/67/12]

(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

[P1968/67/13]

(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 subsection (1) above, 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 Department 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

[P1968/67/14]

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.

## 15 Provision for extending or modifying exemptions

[P1968/67/15]

(1) The Department 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 subsection (1) above may be conferred subject to such conditions or limitations as may be specified in the order.

(3) The Department 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) An order under subsection (3) above shall not have effect until it has been approved by Tynwald.

## 18 Application for licence

[P1968/67/18]

(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) Where documents that constitute a dossier for the purposes of Article 9 of the Second Council Directive 75/319/EEC of 20 May 1975 are forwarded to the licensing authority under and in accordance with the said Article, or documents are forwarded to that authority under and in accordance with Article 17 of Council Directive 81/851/EEC of 28 September 1981, such forwarding shall be deemed to be an application for the grant of a product licence under this Part of this Act.

## 19 Factors relevant to determination of application for licence

[P1968/67/19]

(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; but 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 it thinks 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 compiled with.

(4) Where any such application indicates that the purposes for which the licence 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) above) 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) Subsections (1) to (6) above shall have effect subject to the provisions of this Part of this Act relating to licences of right.

## 20 Grant or refusal of licence

[P1968/67/20]

(1) Subject to section 19 of this Act, 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 it considers appropriate; or

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

(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 or, if for the time being there is no such committee, with the Commission.

(4) Where the licensing authority grants a licence under this Part of this Act, it shall send a copy of the licence to every committee established under section 4 of this Act whose functions consist of or include the giving, in relation to medicinal products of any description to which the licence relates, of advice with respect to safety, quality or efficacy, or, if for the time being there is no such committee, the licensing authority shall send a copy of the licence to the Commission.

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

(a) the licensing authority refuses to grant a licence; or

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

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

## 21 Procedure on reference to appropriate committee or Commission

[P1968/67/21]

(1) Where the appropriate committee or the Commission are consulted with respect to an application for the grant of a licence and it has reason to think, on any grounds relating to the safety, quality or efficacy of a medicinal product to which the licence applied for relates, that it may be unable to advise the licensing authority to grant the licence, or may be unable to advise the licensing authority to grant it unless it contains provisions otherwise than in accordance with the application, the

committee or Commission shall notify the applicant accordingly and, before giving its advice to the licensing authority, shall afford to him an opportunity of appearing before and being heard by it, or of making representations in writing to it with respect to those grounds.

(2) Where the applicant has availed himself of the opportunity of being heard under subsection (1) above, or after considering any representations made by him under that subsection, the appropriate committee or the Commission, as the case may be, shall report to the licensing authority its findings and advice, and the reasons for its advice, and the licensing authority shall take that report into account in determining the application.

(3) Whether the applicant has been heard or has made representations under subsection (1) above or not, if the appropriate committee or the Commission advises the licensing authority that the licence ought on any such grounds as are referred to in that subsection to be refused, or ought, if granted, to contain provisions specified in its advice, the licensing authority shall serve notice on the applicant stating the advice so given to the authority and the reasons stated by the appropriate committee or the Commission for giving that advice.

(4) If, within the time allowed after the service of a notice under subsection (3) above, in a case where the applicant has not been heard by, or made representations to, the Commission under subsection (1) above, he gives notice to the licensing authority to his desire to be heard with respect to the advice given to the authority, or makes representations in writing to the licensing authority with respect to that advice, then, before determining the application —

(a) if the applicant has given notice of his desire to be heard, the licensing authority shall arrange for him to have an opportunity of appearing before, and being heard by, the Commission; or

(b) if he has made representations in writing, the licensing authority shall refer those representations to the Commission,

and, where the applicant has availed himself of the opportunity of being heard, or after considering the representations, as the case may be, the Commission shall report to the licensing authority its findings and advice and the reasons for its advice, and the licensing authority shall take that report into account in determining the application.

(5) If the licensing authority —

(a) proposes to determine the application in a way which differs from the advice of the Commission under subsection (2) or (4) above; or

(b) where there has been no hearing before, and no representations have been made or referred to, the Commission, proposes to determine the application in a way which differs from the advice of the appropriate committee under subsection (2) above; or

(c) in the absence of any such advice as is mentioned in paragraph (a) or (b) above, proposes to determine the application in a way which differs from the advice given by the appropriate committee or the Commission; or

(d) proposes, on grounds not relating to safety, quality or efficacy, to refuse to grant the licence, or to grant a licence otherwise than in accordance with the application,

the licensing authority shall notify the applicant accordingly, and, 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.

(6) Any notification given to the applicant under subsection (5) above —

(a) in a case falling within paragraph (a) or (b) of that subsection, shall state the advice of the Commission or of the appropriate committee and the reasons stated by the Commission or the committee for giving that advice; or

(b) in a case falling within paragraph (c) of that subsection, shall state the advice given by the appropriate committee or the Commission and the reasons stated by the committee or the Commission for giving that advice,

and, in a case falling within paragraph (d) of that subsection (whether it also falls within any of the other paragraphs of that subsection or not), the notification shall include a statement of the proposals of the licensing authority and of the reasons for them.

(7) Where, under subsection (5) above, the applicant avails himself of the opportunity of appearing before, and being heard by, a person appointed for the purpose by the licensing authority —

(a) the person so appointed shall not, except with the consent of the applicant, be an officer or servant of the Department;

(b) if the applicant so requests, the hearing shall be in public; and

(c) if the applicant so requests, the licensing authority shall furnish to him a copy of the report of the person so appointed.

(8) In this Part of this Act, "the time allowed" means the period of twenty-eight days or such extended period as the licensing authority may in any particular case allow.

## 22 Procedure in other cases

[P1968/67/22]

(1) The provisions of this section shall have effect where an application is made for the grant of a licence under this Part of this Act and the provisions of section 21 of this Act do not apply.

(2) If the licensing authority proposes to refuse to grant the licence, or proposes to grant a licence otherwise than in accordance with the application, it shall serve notice on the applicant stating its proposals and the reasons for them.

(3) If, within the time allowed after the service of a notice under subsection (2) above, 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 of his desire to be heard under this subsection, or makes representations in writing to the licensing authority with respect to its 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) Subsection (7) of section 21 of this Act shall have effect in relation to a person appointed under subsection (3) above as it has effect in relation to a person appointed under subsection (5) of that section.

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

[P1968/67/23]

(1) Subject to the provisions of this Part of this Act relating to clinical trials and medicinal tests on animals and 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 which is applicable to medicinal products of that description; or

(b) the products are manufactured or assembled to the order of a person who is the holder of such a product licence,

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

(2) Subject to subsection (3) below, subsection (1) above 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; or

(b) being a veterinary surgeon or veterinary practitioner, states that the product is required for administration to an animal or herd which is under his care or is required, at the request of another veterinary surgeon or veterinary practitioner, for administration to an animal

or herd which is under the care of that other veterinary surgeon or veterinary practitioner,

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) The exemption conferred by subsection (2) above —

(a) in a case falling within paragraph (b) of that subsection; or

(b) in so far as it relates to the manufacture or assembly of a medicinal product to the order of a pharmacist,

does not apply to a vaccine specially prepared for administration to poultry.

(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) above shall have effect subject to such exceptions or modifications as the Department consider appropriate in the circumstances.

(5) Where subsection (1) above 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) Notwithstanding anything contained in this section, the licensing authority may direct that this section shall not have effect in any particular case or class of cases, and any such direction shall have effect accordingly.

## 24 Duration and renewal of licence

[P1968/67/24]

(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, 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 licensing 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 the 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) above; or

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

(c) if, having regard to the provisions of this Act, it considers 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, 19, 20(2) to (5), 21 and 22 of this Act shall have effect as if in those provisions any reference to refusing a licence included a reference to refusing a 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 (2) above, as the case may be; and, in this Part of this Act, any reference (including a reference implied by virtue of subsection (4) above) 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 has determined the application; and

(b) if, by an interim order made under section 101(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.

*Suspension revocation and variation of licences*

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

[P1968/67/28]

(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) 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 Island;

(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) that any of the provisions of the licence, in so far as they relate to the incorporation in animal feeding stuffs of any medicinal product are not in accordance with any Community obligation;

(j) that, in relation to medicinal products of any description to which the licence relates 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.

(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) above, 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) above, 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) Subsections (1) to (6) above shall have effect subject to section 29 of this Act.

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

[P1968/67/29]

(1) The provisions of Schedule 2 to this Act shall have effect where the licensing authority proposes 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 suspends, revokes or varies a licence, it shall serve on the holder of the licence a notice giving particulars of the suspension, revocation or variation and of the reasons for its decision to suspend, revoke or vary the licence.

### 30 Variation of licence on application of holder

[P1968/67/30]

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 it is satisfied that the variation will not adversely affect the safety, quality or efficacy of medicinal products of any description to which the licence relates.

### 34 Restrictions as to animals on which medicinal tests have been carried out

[P1968/67/34]

(1) Subject to the following provisions of this Act, no person shall, in the course of a business carried on by him, sell or supply for human consumption an animal to which, in the course of that business, a substance or article has been administered by way of a test to which this section applies, or the carcase or any part of the carcase or any produce of such an animal, unless —

(a) at the time when the substance or article was so administered there was in force an animal test certificate issued in respect of that test; and

(b) all the provisions of that certificate relating to the carrying out of the test and the disposal of the animal or its carcase or produce are, and have at all material times been, complied with

(2) This section applies to any medicinal test on animals which is carried out in the course of the business of the person who has manufactured the substance or article administered in the test, or is carried out on his behalf in the course of the business of a laboratory or research establishment carried on by another person, and (in either case) is so carried out on one or more animals kept in the course of the business of the person carrying out the test.

## 44 Provision of information to licensing authority

[P1968/67/44]

(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) or for a clinical trial certificate or animal test certificate (including a certificate to which a person is entitled by virtue of section 37(4) of this Act), 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 it; or

(b) it has been shown to the licensing authority's 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, or of a clinical trial certificate or animal test certificate, 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) below, a notice under subsection (2) above shall not be served unless it appears to the licensing authority, or it is represented to it by the Commission or by the appropriate committee, that circumstances exist by reason of which it is necessary to consider whether the licence or certificate 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 it by the Commission or by the committee, to be requisite for considering that question.

(4) Subsection(3) above shall not have effect in the case of a licence of right, or of a certificate issued in pursuance of section 37(4) of this Act, whether the

licence or certificate has been renewed or not; and, in the case of such a licence or certificate, a notice under this section may be served at an time, and may require any information which, in the opinion of the licensing authority, would be relevant if —

(a) sections 25 and 37(4) 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 or issue 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 Island 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

[P1968/67/45]

(1) Subject to section 46 of this Act, any person who contravenes any of the provisions of sections 7, 8, 31, 32, 34 or 40 of this Act, or who is in possession of any medicinal product or animal feeding stuff for the purpose of selling, supplying or exporting it in contravention of any of those sections, shall be guilty of an offence.

(2) Where any medical product or animal feeding stuff is imported in contravention of section 7, 31, 32 or 40 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 or feeding stuff 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 or of a clinical trial certificate or animal test certificate, procures another person to carry out a process in the manufacture or assembly of medicinal products of a description to which the licence or certificate relates, and —

(a) does not communicate to that person the provisions of the licence or certificate 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) Any person who, being the holder of a product licence or of an animal test certificate, sells or supplies a substance or article to which the licence or certificate relates to another person for the purpose of its being incorporated in any animal feeding stuff, and does not communicate to that person any provisions of the licence or certificate which relate to the incorporation of that substance or article in animal feeding stuffs, or any instructions required by the licence to be communicated by him to persons to whom the substance or article is sold or supplied for that purpose, shall be guilty of an offence.

(5) Where any such provisions of a product licence or animal test certificate as are mentioned in subsection (4) above are varied by the licensing authority, and on varying those provisions the licensing authority serves on the holder of the licence or certificate a notice requiring him, within such time (not being less than fourteen days from the date of service of the notice) as may be specified in the notice, to take such steps as may be so specified for making the variation known, either generally or to persons or classes of persons specified in the notice, then, if the holder of the licence or certificate does not comply with the requirements of that notice, he shall be guilty of an offence.

(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) above shall be liable —

(a) on summary conviction, to a fine not exceeding £5,000;

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

(9) Any person guilty of an offence under subsection (7) above shall be liable on summary conviction to a fine not exceeding £1,000.

## 46 Special defences under s 45

[P1968/67/46]

(1) Where the holder of product licence or of a clinical trial certificate or animal test certificate is charged with an offence under section 45 of this Act 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 or certificate 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 section 45 of this Act 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 or of a clinical trial certificate or animal test certificate 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, or of a clinical trial certificate or animal test certificate applicable to them; and

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

(3) and (4) [Repealed]

## 47 Standard provisions for licences or certificates

[P1968/67/47]

(1) The Department 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 or any clinical trial certificate or animal test certificate granted or issued 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)) above, '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, or any clinical trial certificate or animal test certificate, which is in force at the end of that period or, in the case of a suspended licence or certificate, 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 or certificate relates.

(5) Notwithstanding anything in subsection (4) above, the operative standard provisions shall not, by virtue of that subsection, be deemed to be incorporated in any licence of right, or in any certificate issued in pursuance of section 37(4) of this Act, including any such licence or certificate which has been renewed, except in circumstances where, immediately before the first appointed day, the manufacture or importation of substances of articles to which the licence or certificate relates was authorised by a licence issued under Part 1 of the Therapeutic Substances Act 1957 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 or certificate 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 certificate; 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 directs 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) above.

(7) Where an application is made to the licensing authority under subsection (6) above, then, if the licensing authority proposes 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 determines to refuse to give a direction in accordance with the application, it shall serve on the applicant a notice stating the reasons for its decision.

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

(a) the operative standard provisions shall not be deemed to be incorporated in the licence or certificate to which the application relates before the licensing authority has made a decision on that application; and

(b) if an application under section 101 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) above has been finally disposed of;

and so much of the 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 or certificate shall be exercisable with respect to any provisions which, in accordance with this section, are incorporated or deemed to be incorporated in a licence or certificate.

## ENDNOTES

### Table of Endnote References

[1] Subs (1) amended by SD155/10 Sch 4, by SD2014/08 and by SD2019/0102 with effect from 31/12/2020 at 23:00.
[2] Definition of "Community authorisation" repealed by SD2019/0102 with effect from 31/12/2020 at 23:00.
[3] Definition of "EU authorisation" inserted by SD2019/0102 with effect from 31/12/2020 at 23:00.
[4] Para (a) substituted by SD2019/0102 with effect from 31/12/2020 at 23:00.
[5] Para (b) substituted by SD2019/0102 with effect from 31/12/2020 at 23:00.
[6] Para (f) amended by Medicines (Amendment) Act 2021 s 3. [Editorial Note: By virtue of section 4(1), amendments made by the Medicines (Amendment) Act 2021 are deemed to have been in operation when the Prescription Only Medicines (Human Use) Regulations 2005 (SD 11/05) (which apply the Prescription Only Medicines (Human Use) Order 1997 (of Parliament) to the Island), were made on 09/12/2005.]
[7] Para (g) inserted by Medicines (Amendment) Act 2021 s 3. [Editorial Note: By virtue of section 4(1), amendments made by the Medicines (Amendment) Act 2021 are deemed to have been in operation when the Prescription Only Medicines (Human Use) Regulations 2005 (SD 11/05) (which apply the Prescription Only Medicines (Human Use) Order 1997 (of Parliament) to the Island), were made on 09/12/2005.]
[8] Para (a) amended by SD2019/0102 with effect from 31/12/2020 at 23:00.
[9] Para (b) substituted by SD2019/0102 with effect from 31/12/2020 at 23:00.
[10] Subs (1) amended by Medicines (Amendment) Act 2021 s 3. [Editorial Note: By virtue of section 4(1), amendments made by the Medicines (Amendment) Act 2021 are deemed to have been in operation when the Prescription Only Medicines (Human Use) Regulations 2005 (SD 11/05) (which apply the Prescription Only Medicines (Human Use) Order 1997 (of Parliament) to the Island), were made on 09/12/2005.]
[11] Subs (1) amended by SD2019/0102 with effect from 31/12/2020 at 23:00.
[12] Subs (1) amended by SD2019/0102 with effect from 31/12/2020 at 23:00.
[13] Subs (2) substituted by Medicines (Amendment) Act 2021 s 3. [Editorial Note: By virtue of section 4(1), amendments made by the Medicines (Amendment) Act 2021 are deemed to have been in operation when the Prescription Only Medicines (Human Use) Regulations 2005 (SD 11/05) (which apply the Prescription Only Medicines (Human Use) Order 1997 (of Parliament) to the Island), were made on 09/12/2005.]
[14] Subs (2A) inserted by Medicines (Amendment) Act 2021 s 3. [Editorial Note: By virtue of section 4(1), amendments made by the Medicines (Amendment) Act 2021 are deemed to have been in operation when the Prescription Only Medicines (Human Use) Regulations 2005 (SD 11/05) (which apply the Prescription Only Medicines (Human Use) Order 1997 (of Parliament) to the Island), were made on 09/12/2005.]
[15] Subs (2B) inserted by Medicines (Amendment) Act 2021 s 3. [Editorial Note: By virtue of section 4(1), amendments made by the Medicines (Amendment) Act 2021 are deemed to have been in operation when the Prescription Only Medicines (Human Use)

Regulations 2005 (SD 11/05) (which apply the Prescription Only Medicines (Human Use) Order 1997 (of Parliament) to the Island), were made on 09/12/2005.]

[16] S 5A inserted by Medicines (Amendment) Act 2021 s 3. [Editorial Note: By virtue of section 4(1), amendments made by the Medicines (Amendment) Act 2021 are deemed to have been in operation when the Prescription Only Medicines (Human Use) Regulations 2005 (SD 11/05) (which apply the Prescription Only Medicines (Human Use) Order 1997 (of Parliament) to the Island), were made on 09/12/2005.]

[17] Definition of "authorisation" repealed by SD2019/0102 with effect from 31/12/2020 at 23:00.

[18] Subs (3) amended by Civil Partnership Act 2011 Sch 14.

[19] Subpara (ii) amended by SD2023/0185.

[20] Subs (1) amended by Medicines (Amendment) Act 2021 s 3. [Editorial Note: By virtue of section 4(1), amendments made by the Medicines (Amendment) Act 2021 are deemed to have been in operation when the Prescription Only Medicines (Human Use) Regulations 2005 (SD 11/05) (which apply the Prescription Only Medicines (Human Use) Order 1997 (of Parliament) to the Island), were made on 09/12/2005.]

[21] Subs (1) amended by Medicines (Amendment) Act 2021 s 3. [Editorial Note: By virtue of section 4(1), amendments made by the Medicines (Amendment) Act 2021 are deemed to have been in operation when the Prescription Only Medicines (Human Use) Regulations 2005 (SD 11/05) (which apply the Prescription Only Medicines (Human Use) Order 1997 (of Parliament) to the Island), were made on 09/12/2005.]

[22] S 31 not yet in force.

[23] Para (a) repealed by SD2019/0102 with effect from 31/12/2020 at 23:00.

[24] Subs (3A) inserted by Medicines (Amendment) Act 2021 s 3. [Editorial Note: By virtue of section 4(1), amendments made by the Medicines (Amendment) Act 2021 are deemed to have been in operation when the Prescription Only Medicines (Human Use) Regulations 2005 (SD 11/05) (which apply the Prescription Only Medicines (Human Use) Order 1997 (of Parliament) to the Island), were made on 09/12/2005.]

[25] Subs (4) amended by SD155/10 Sch 3.

[26] S 32 not yet in force.

[27] S 33 not yet in force.

[28] S 34 not yet in force.

[29] S 36 substituted by SD2023/0185.

[30] Subs (1) substituted by SD2023/0185.

[31] Subs (3) inserted by SD2023/0185.

[32] Subs (4) inserted by SD2023/0185.

[33] Subs (5) inserted by SD2023/0185.

[34] Subs (6) inserted by SD2023/0185.

[35] Subs (7) inserted by SD2023/0185.

[36] Subs (8) inserted by SD2023/0185.

[37] Para (b) substituted by SD2023/0185.

[38] Subs (2A) inserted by SD2023/0185.

[39] Subs (2B) inserted by SD2023/0185.

[40] Subs (2C) inserted by SD2023/0185.

[41] Subs (2D) inserted by SD2023/0185.

[42] Para (b) repealed by SD2023/0185.

[43] Para (b) amended by SD2023/0185.

[44] See addendum.

[45] ADO (whole Act, except Parts 3 and 5) 1/11/2004 [SD761/04]; Part 3 in operation 01/07/2018 [SD2018/0152] .

[46] Para 12 amended by Interpretation Act 2015 s 106.

[47] Item (a) amended by Interpretation Act 2015 s 107.

[48] Entry inserted by Medicines (Amendment) Act 2021 s 3. [Editorial Note: By virtue of section 4(1), amendments made by the Medicines (Amendment) Act 2021 are deemed to have been in operation when the Prescription Only Medicines (Human Use) Regulations 2005 (SD 11/05) (which apply the Prescription Only Medicines (Human Use) Order 1997 (of Parliament) to the Island), were made on 09/12/2005.]

[49] Entry inserted by SD2019/0102 with effect from 31/12/2020 at 23:00.

[50] Entry repealed by SD2019/0102 with effect from 31/12/2020 at 23:00.

[51] Entry substituted by SD2019/0102 with effect from 31/12/2020 at 23:00.

[52] Definition of "the Department" amended by SD155/10 Sch 4 and by SD2014/08.

[53] Definition of "doctor" substituted by Health Care Professionals Act 2014 s 14.

[54] Entry substituted by SD2019/0102 with effect from 31/12/2020 at 23:00.

[55] Definition of "registered" repealed by Interpretation Act 2015 s 105.

[56] Para (d) substituted by SD2019/0102 with effect from 31/12/2020 at 23:00.

[57] Definition of "veterinary practitioner" repealed by Veterinary Surgeons Act 2005 Schs 2 and 3.