ORDER IN COUNCIL

V
2009

ratifying a Projet de Loi

ENTITLED

The Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008

(Registered on the Records of the Island of Guernsey
on the 27th January, 2009.)

2009

Printed by Image Group, Pitronnerie Road, Guernsey

ORDER IN COUNCIL

IN THE ROYAL COURT OF THE ISLAND OF GUERNSEY

27th day of January, 2009 before Geoffrey Robert Rowland, Esquire, Bailiff; present:- Derek Martin Le Page, Stephen Edward Francis Le Poidevin, Alan Cecil Bisson, The Reverend Peter Gerald Lane, Michael Henry De La Mare, Michael John Tanguy, Esquires, Susan Mowbray, Barbara Jean Bartie, David Osmond Le Conte, Stephen Murray Jones Esquires, and Claire Helen Le Pelley, Jurats.

The Bailiff having this day placed before the Court an Order of Her Majesty in Council dated 10th December 2008 approving and ratifying a Projet de Loi entitled "The Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008", THE COURT, after the reading of the said Order in Council and after having heard Her Majesty's Procureur thereon, ORDERED: -

1. That the said Order in Council be registered on the records of this Island;
   and
2. That an extract of this present Act, together with a copy of the said Order in Council be sent by Her Majesty's Greffier to the Greffier of the Court of Alderney and to the Sénéschal of Sark for registration on the records of those Islands respectively.

At the Court at Buckingham Palace

THE 10th DAY OF DECEMBER 2008

PRESENT,

THE QUEEN'S MOST EXCELLENT MAJESTY
IN COUNCIL

The following report from the Committee of Council for the Affairs of Jersey and Guernsey was today read at the Board:

"In accordance with Your Majesty's General Order of Reference of 22nd February 1952 the Committee have considered a Petition of the States of Guernsey:

"That, in pursuance of their Resolution of 29th September 2004, the States of Deliberation at a meeting on 27th February 2008 approved a Projet de Loi entitled The Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008 and requested the Bailiff to present a most humble Petition to Your Majesty in Council praying for Your Royal Sanction to it. That the States of the Island of Alderney at a meeting held on 19th March 2008 considered the Projet de Loi when a Resolution was passed agreeing to the application to Alderney. That the Chief Pleas of the Island of Sark at a meeting held on 26th March 2008 considered the Project de Loi when a Resolution was passed agreeing to the application to Sark. That the Project de Loi as set forth in the attached Schedule. The Petition most humbly prays that Your Majesty might be graciously pleased to sanction The Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008 and to order that it shall have force of law in the Bailiwick of Guernsey.

"The Committee have considered the Projet de Loi and have agreed to report that it may be advisable for Your Majesty to approve and ratify it".

Her Majesty, having taken the report into consideration, was pleased, by and with the advice of Her Privy Council, to approve and ratify the Projet de Loi (a copy of which is annexed to this Order) and to order that it, together with this Order, shall have the force of law in the Bailiwick of Guernsey and shall be entered on the Register of the Island of Guernsey and observed accordingly.

Her Majesty's Officers in the Bailiwick of Guernsey, and all others whom it may concern, are therefore to take notice of Her Majesty's Order and to proceed accordingly.

Judith Simpson

The Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008

ARRANGEMENT OF SECTIONS

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PROJET DE LOI

ENTITLED

The Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008

THE STATES, in pursuance of their Resolution of 29th September, 2004[a], have approved the following provisions which, subject to the Sanction of Her Most Excellent Majesty in Council, shall have force of law in the Bailiwick of Guernsey.

PART I
ADMINISTRATION

Department responsible for administration of the Law.

1. In this Law, except where the contrary is expressly provided -

(a) "**the Department**" means the Health and Social Services Department, and

(b) "**the appropriate Department**" means the Department or, for the purposes of any matters relating to poisons, veterinary medicinal products, animal feeding stuffs, or any medicinal tests on animals, the Commerce and Employment Department, as the context requires.

Establishment of the Medicines Committee.

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[a] Article XIV on Billet d'État No. XIV of 2004.

2. (1) There shall be established a body of persons to be called the Medicines Committee (referred to in this Law as "**the Committee**") to perform the functions assigned to the Committee by or under this Law.

(2) The Department shall appoint the members of the Committee.

(3) The members of the Committee shall comprise -

(a) the Chief Pharmacist,

(b) the Director of Public Health,

(c) the States Veterinarian,

(d) the Department's Professional Head of Nursing,

(e) a nominee of the Chief Officer of the Department,

(f) one or more lay people (as the Department considers appropriate).

(4) The Department shall appoint -

(a) the Chief Pharmacist to be the Secretary of the Committee, and

(b) one of the members of the Committee to be chairman of the Committee.

Functions of the Committee.

3. (1) The Committee shall advise the Department on matters -

(a) relating to the execution of this Law,

(b) relating to the exercise of any power conferred by or under this Law, or

(c) otherwise relating to the regulation of medicinal products,

where either the Committee consider it expedient, or they are requested by the Department, to do so.

(2) Without prejudice to subsection (1), or to any other duties or powers imposed or conferred on the Committee by or under this Law or any other enactment, it shall be the duty of the Committee -

(a) to give advice with respect to -

(i) safety, quality and efficacy in relation to medicinal products, and

(ii) local practice regarding the manufacturing, wholesale distribution and dispensing of medicinal products in the Bailiwick,

(b) to promote the collection and investigation of information relating to adverse reactions, for the purposes of enabling the advice in paragraph (a) to be given,

(c) to undertake any other function related to the regulation of medicinal products which may be conferred by this Law or any enactment made

thereunder except in so far as those functions may otherwise be assigned to a committee established under section 4 (establishment of sub-committees), and

(d) to advise the regulatory authority in cases where -

(i) it is required by the provisions of Part II (Regulatory provisions relating to medicinal products), or by the provisions of any other enactment, to consult the Committee with respect to any matter arising under those provisions, or

(ii) it so requests, in relation to any matter arising under any of the provisions referred to in sub paragraph (i).

Establishment of sub-committees.

4. (1) The appropriate Department, shall, by order establish two sub-committees of the Committee under this section, which shall, respectively, be named -

(a) "**the sub-committee for human medicines**" and

(b) "**the sub-committee for animal medicines**", or

such other names as may be specified in the order.

(2) The two sub-committees shall be so established for any purpose, or combination of purposes, connected with -

(a) the execution, or

(b) the exercise of any power conferred by or under this Law,

either generally, or in relation to any particular class of substances or articles to which any provision applies.

(3) Without prejudice to the generality of subsection (2), in relation to any such class of substances or articles further sub-committees may be established under this section by order of the appropriate Department, for any or all of the following purposes -

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

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

(c) giving advice with respect to any other issue related to medicinal products that the Committee may consider appropriate.

(4) The sub-committee for human medicines shall comprise the following members -

(a) a practising medical practitioner,

(b) a dentist,

(c) a pharmacist,

(d) a lay person, and

(e) the Chief Inspector, acting ex officio.

(5) The sub-committee for animal medicines shall comprise the following members -

(a) a practising veterinary surgeon,

(b) a person involved in animal husbandry,

(c) a nominee of the Chief Officer of the appropriate Department,

(d) a lay person, and

(e) the States Veterinarian, acting ex officio.

(6) The appropriate Department by which a sub-committee is established shall appoint the members of the sub-committee, and shall appoint one of those members to be chairman of the sub-committee.

(7) In this Law "**the appropriate committee**", for the purposes of any provision under which a function falls to be performed, means -

(a) in a case where -

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

(ii) the appropriate Department considers it to be the appropriate sub-committee in the circumstances,

that sub-committee, and

(b) in any other case, the Committee.

Supplementary provisions as to Committee and sub-committees.

5. (1) The provisions of Schedule 1 (Provisions relating to committee and sub-committees) have effect.

(2) The Committee shall, at such time in each year as the Department may direct, send a report to the Department with respect to the performance of its functions and the Department shall lay before the States a copy of every such report.

(3) Each sub-committee established under section 4 (Establishment of sub-committees) shall, at such time in each year as the Committee may direct, send to the Committee a report with respect to the performance of its functions.

(4) Subject to subsection (5), the Department, after consultation with the Committee, may by order -

(a) add to, revoke or vary any of the provisions of Schedule 1 to this Law in its application to the Committee or any sub-committee,

(b) confer on the Committee or any sub-committee any new function for purposes connected with the regulation of medicinal products or related matters,

(c) terminate any function conferred on the Committee or any sub-committee by or under this Law, or

(d) vary any such function, so however as not to confer on the Committee or sub-committee any new function which could not be conferred on them in accordance with paragraph (b).

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

PART II
REGULATORY PROVISIONS RELATING TO MEDICINAL PRODUCTS

General provisions and exemptions

The regulatory authority.

6. (1) For the purposes of this Part, the authority responsible for any recognition, grant, renewal, variation, suspension and revocation of licences, authorisations and certificates, shall be the Department ("**the regulatory authority**").

(2) In exercising those functions, the Department shall act in consultation with -

(a) the Chief Inspector, and

(b) the MHRA.

General provisions as to dealing with medicinal products.

7. (1) The following provisions have effect subject to -

(a) any exemption conferred by or under this Part,

(b) the provisions of Part VII (Veterinary medicinal products and veterinary surgeons),

(c) any regulations made under paragraph 12 of Schedule 2 (Clinical trials in respect of medicines for human use), in relation to clinical trials,

(d) the provisions of section 24 (Postponement of restrictions in relation to exports), and

(e) any further provisions that the Department may specify by regulations made under subsection (3).

(2) Subject to the following provisions, no person shall, in the course of a business carried on by him -

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

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

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

(d) otherwise place any medicinal product on the market in the Bailiwick,

unless the regulatory authority has recognised a marketing authorisation or recognised or granted a licence for the medicinal product concerned.

(3) The Department shall, by regulations, specify the circumstances in which a person shall not require a licence or in which a licence or marketing authorisation is recognised, subject to such conditions, as may be specified.

(4) No person shall import or export any medicinal product except in accordance with the provisions of -

(a) the Customs and Excise (General Provisions) (Bailiwick of Guernsey) Law, 1972[b], the Import and Export (Control) (Guernsey) Law, 1946[c], the Export Control (Bailiwick of Guernsey) Law[d], the Misuse of Drugs (Guernsey) Law 1974[e], the Poisonous Substances (Guernsey) Law 1994[f], the Import and

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b Ordres en Conseil Vol. XXIII, p. 573; Vol XXIV, P. 87; Vol. XXXI, p. 278; No. XIII of 1991; No. X of 2004 and Ordinance No. XXXII of 2004.

c Ordres en Conseil Vol. XII, p. 332 and as amended by Vol. XXIII, p. 573; and No. XVI of 1991.

d Order in Council No. XIV of 2007

e Ordres en Conseil, Vol. XXIV, p. 273; Vol. XXVIII, p. 307; Vol. XXXI, p.47; No. XIII of 1991; No. V of 1992; No. XVI of 1995; No. III of 2000; No. VII of 2000; No IV of 2006; No. XIII of 2006 and Recueil d'Ordonnances Tome No. IX, p.270.

f Order in Council No.XVIII of 1994; No. XXXI of 1996; and Ordinance No. XXVIII of 1995.

Export (Control) Alderney Law, 1946[g] and the 1950 Order in Council concerning Sark Duties[h],

(b) any licence, recognised licence or recognised marketing authorisation and any terms and conditions of any licence, recognition or authorisation, and

(c) any regulations made by the Department under subsection (3).

(5) The restrictions imposed by subsections (2) and (4) shall not apply where the medicinal product concerned is -

(a) an investigational medicinal product within the meaning of any regulations made under paragraph 12 of Schedule 2 (Clinical trials in respect of medicines for human use),

(b) a homoeopathic medicinal product to which the 2001 Directive applies and which fulfils the conditions laid down in Article 14(1) of that Directive, or

(c) a radiopharmaceutical in which the radionuclide is in the form of a sealed source.

(6) In this section -

"**homoeopathic medicinal product**" means any medicinal product (which may contain a number of principles) prepared from substances called

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g Ordres en Conseil Vol. XII, p. 367.

h Ordres en Conseil Vol. XIV, p.366.

homoeopathic stocks in accordance with a homoeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by any pharmacopoeia used officially in any EU member State, or any other country or territory that the Department may, by order, specify,

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

"**the 2001 Directive**" means Directive 2001/83/EC.

Provisions as to manufacture and wholesale dealing.

8. (1) The provisions of this section have effect without prejudice to the operation of section 7 (General provisions as to dealing with medicinal products), but subject to the exemptions and provisions referred to in subsections 7(1)(a) to (e).

(2) Subject to subsections (3) and (5), and any exemption conferred by or under this Part, no person shall, in the course of a business carried on by him, manufacture, assemble or import a medicinal product, from any country which is not -

(a) a Member State of the European Union, or

(b) a country or territory specified by the Department, by order,

except in accordance with a licence granted or recognised for the purposes of this subsection (in this Law referred to as a "**manufacturer's licence**").

(3) In the case of a medicinal product that is an investigational medicinal product, the restrictions imposed by subsection (2) only apply -

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

(b) to the extent that the manufacture or assembly of the product is in accordance with the terms and conditions of that recognised authorisation or equivalent.

(4) In subsection (3) -

"**investigational medicinal product**" means a pharmaceutical form of an active substance or placebo being tested, or to be tested, or used, or to be used, as a reference in a clinical trial, and includes a medicinal product which has a marketing authorisation, or equivalent but is, for the purposes of the trial -

(a) used or assembled (formulated or packaged) in a way different from the form of the product authorised under the authorisation,

(b) used for an indication not included in the summary of product characteristics under the authorisation for that product, or

(c) used to gain further information about the form of that product as authorised under the authorisation, and

"**or equivalent**" means -

(a) a marketing authorisation granted by the European Commission or the Agency under Council Regulation 726/2004/EC or

(b) any other authorisation granted by any organisation, country or territory that the Department may, by order, specify.

(5) The prohibition in subsection (2) does not apply to a person who, in connection with the importation of a medicinal product from a country that is not a Member State of the European Union -

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

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

(6) The Department may prescribe requirements (either generally or in relation to a prescribed class of medicinal product or activity) -

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

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

(7) Subject to subsections (10) and (11) no person shall, in the course of a business carried on by him -

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

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

(i) from a Member State of the European Union, or

(ii) any other country or territory that the Department may, by order, specify,

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

(8) Without prejudice to the generality of subsection (7) but subject to subsections (10) and (11) no person shall, in the course of a business carried on by him, distribute by way of wholesale dealing a medicinal product except in accordance with a wholesale dealer's licence or recognition of that licence.

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

(10) The restrictions imposed by subsections (7) and (8) do not apply -

(a) where the Department specifies particular circumstances, by order, to anything done in relation to a product to which the 2001 Directive applies by the holder of a manufacturer's licence in respect of it, or

(b) where the product concerned is an investigational medicinal product within the meaning of any regulations made under paragraph 12 of Schedule 2.

(11) The Department may prescribe requirements (either generally or in relation to a prescribed class of medicinal product or activity) -

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

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

(12) Subsection (7)(b) shall not apply if the product is a radiopharmaceutical in which the radionuclide is in the form of a sealed source.

(13) In this section –

"**homoeopathic medicinal product**" has the same meaning as in section 7,

"**proprietary medicinal product**" means a ready-prepared medicinal product placed on the market in the Bailiwick under a special name and in a special pack, and

"**radiopharmaceutical**" has the same meaning as in section 7.

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

(a) selling or supplying it, or

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

to a person who receives it for the purposes of -

(i) selling or supplying it, or

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

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

(15) In this Law any reference to a wholesale dealer's licence or recognition of that licence is a reference to a licence granted or recognised for the purposes of subsection (7) or (8).

(16) The provisions of this section do not apply to the Department.

Exemptions for doctors and dentists.

9. The restrictions imposed by sections 7 (General provisions as to dealing with medicinal products) and 8 (Provisions as to manufacture and wholesale dealing), 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.

Exemptions for pharmacists.

10. (1) The restrictions imposed by sections 7 (General provisions as to dealing with medicinal products) and 8 (Provisions as to manufacture and wholesale dealing), do not apply to anything -

(a) which is done by, or under, the supervision of a pharmacist, and

(b) which takes place in a registered pharmacy, a hospital, a nursing or residential home, and

(c) which consists of -

(i) preparing or dispensing a medicinal product -

(A) in accordance with a prescription given by a practitioner, and

(B) in accordance with any directions which may be given by the Committee, or

(ii) assembling a medicinal product, provided that where the assembling takes place in a registered pharmacy-

(A) 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

(B) the medicinal product has not been the subject of an advertisement,

and those restrictions do not apply to anything done by, or under, the supervision of a pharmacist which consists of procuring the preparation or dispensing of a medicinal product in accordance with a prescription given by a practitioner and with any directions given by the Committee, or of procuring the assembly of a medicinal product.

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

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

(a) preparing or dispensing a medicinal product for administration to a person where -

(i) 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,

(ii) that person is present in the pharmacy at the time of the request in pursuance of which that product is prepared or dispensed, and

(iii) any directions which may have been given by the Committee are complied with, or

(b) preparing a stock of medicinal products with a view to dispensing them as mentioned in subsection (1)(c)(i) or (2) or in paragraph (a) provided that -

(i) such stock is prepared with a view to retail sale or to supply in circumstances corresponding to retail sale, and

(ii) the preparation is done with a view to such sale or supply taking place 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 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)(c)(i).

(4) Without prejudice to the preceding subsections, the restrictions imposed by section 7, 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.

(5) Without prejudice to the preceding subsections, the restrictions imposed by section 8(2), do not apply to anything which is done in a registered pharmacy, or in a hospital 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.

(6) Without prejudice to the preceding subsections, the restrictions imposed by sections 8(7) or 8(8), do not apply to anything which is done in a registered pharmacy, or in a hospital 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 or where such dealing is carried out on a hospital premises for reasons of public policy.

(7) The Department may, by order, prescribe conditions which must be complied with or circumstances in which, for the purposes of this section, a thing is to be considered as having been done under the supervision of a pharmacist.

(8) In this section –

"**advertisement**" has the meaning given by section 72 (scope of Part VI), except that it shall not include words inscribed on the medicinal product, or on its container or package,

"**hospital**" means any hospital operated or registered by the Department, and

"**nursing or residential home**" has the meaning given by section 18(1) of the Nursing Homes and Residential Homes (Guernsey) Law, 1976[i].

Exemptions for midwives, certain nurses and other authorised persons.

11. The restrictions imposed by section 8 (Provisions as to manufacture and wholesale dealing), do not apply to the assembly of any medicinal products by a person in the course of that person's profession as -

(a) a registered midwife,

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[i] Ordres en Conseil Vol. XXVI, p. 71.

(b) a district or community nurse,

(c) a health visitor,

(d) a nurse prescriber, or

(e) any other profession that the Department may, by Ordinance, specify.

Exemptions in respect of herbal remedies.

12. (1) The restrictions imposed by sections 7 (General provisions as to dealing with medicinal products) and 8 (Provisions as to manufacture and wholesale dealing), do not apply to the sale, supply, preparation or assembly of any herbal remedy in the course of a business where -

(a) the remedy is prepared 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.

(3) The Department may, by order, specify other circumstances in which herbal remedies which are sold, supplied, prepared or assembled are exempt from the restrictions imposed by sections 7 and 8..

(4) The Department may, by Ordinance, specify other circumstances in which herbal remedies which are manufactured are exempt from the restrictions imposed by sections 7 and 8.

Exemptions for imports.

13. (1) Subject to subsection (2), the restriction imposed by section 7(4) (General provisions as to dealing with medicinal products), does not apply to the importation of a medicinal product -

(a) by any person for administration to himself or to any person or persons who are members of his household,

(b) where the product is specially imported by or to the order of a doctor or dentist for administration to a particular patient of his,

(c) where the product is specially imported by the appropriate Department for reasons of public policy, or

(d) in such circumstances as may otherwise be prescribed by the Department by order.

(2) The exemptions under subsections (1)(a) and (b) shall have effect only where the quantity of the importation does not exceed an amount equivalent to that required for 6 months personal supply of the medicinal product concerned under normal prescribed doses.

Exemptions for re-exports.

14. The Department may, by order, make provisions exempting medicinal products which are re-exported, from any of the restrictions imposed under sections 7 (General provisions as to dealing with medicinal products) and 8 (Provisions as to manufacture and wholesale dealing).

Provision for extending or modifying exemptions.

15. (1) The Department may by order provide that sections 7 (General provisions as to dealing with medicinal products) and 8 (Provisions as to manufacture and wholesale dealing), shall have effect subject to such exemptions (other than those for the time being having effect by virtue of sections 9 to 14 (exemptions)) or any enactment made under them, as may be specified in the order.

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

(3) The Department may by Ordinance provide that any of the provisions of sections 9 to 14 shall cease to have effect, or shall have effect subject to such exceptions or modifications as may be specified.

Transitional exemptions.

16. (1) The restrictions imposed by sections 7 (General provisions as to dealing with medicinal products) and 8 (Provisions as to manufacture and

wholesale dealing), do not apply to anything done before such day as the Department may by order appoint for the purposes of this subsection (in this Law referred to as "**the first appointed day**"); and, except as otherwise provided by any order made under section 17 (Termination of transitional exemptions), the following provisions shall have effect in relation to things done on or after that day.

(2) Section 7(2), shall not have effect in relation to a person in respect of his selling or supplying, or procuring the sale, supply, manufacture or assembly of, medicinal products of any description if -

(a) in the course of a business carried on by him, any medicinal products of that description were sold or supplied, or procured to be sold, supplied, manufactured or assembled, at any time before the first appointed day, and

(b) medicinal products of that description were effectively on the market in the Bailiwick immediately before the first appointed day, and either -

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

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

(3) Section 7(4), shall not have effect in relation to a person in respect of his importing medicinal products of any description in the course of a business carried on by him if, in the course of that business, medicinal products of that description were imported within the period of twenty-four months ending with the first appointed day.

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

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

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

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

(5) Section 8(3) shall not have effect in relation to a person in respect of his selling or offering for sale any medicinal products by way of wholesale dealing in the course of a business carried on by him if, in the course of that business, medicinal products were being sold or offered for sale by way of

wholesale dealing within the period of twelve months ending with the first appointed day.

Termination of transitional exemptions.

17. For the purposes of sections 16(2) to (5) (Transitional exemptions) the Department may by one or more orders under this section or under Schedule 2 appoint one or more days, subsequent to the first appointed day, and may by any such order provide that such one or more of those subsections as may be specified in that order shall cease to have effect either -

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

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

Applications for recognition, grant and renewal etc. of licences.

18. The provisions of Schedules 2 and 3 shall have effect.

Supplementary provisions

Extension of section 7 to certain special circumstances.

19. (1) Where in the course of a business carried on by him a person sells, supplies or exports a substance or article for use as specified in section 133(1) (Meaning of "**medicinal product**" and related expressions), and the substance or article, not having been -

(a) manufactured or imported for such use, or

(b) previously sold or supplied for such use,

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

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

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

(4) Where in the course of a business carried on by him, a person proposes to sell, supply or export a substance or article for use as mentioned in subsection (1), where the substance or article will not constitute a medicinal product before he so sells, supplies or exports it and he will not be selling, supplying or exporting it in circumstances to which section 7(2), applies, the Department may make regulations specifying the circumstances in which he, or any class or description of persons, may be permitted to sell, supply or export that substance or article, or any class or description of substances or articles.

(5) In subsection (2) the reference to assembling a substance or article in the course of a business carried on by a person is a reference to doing in the course of that business anything which (in accordance with section 136(1) (General interpretation provisions)) would constitute assembling if it had been a medicinal product when sold or supplied to him.

Provision of information to regulatory authority.

20. (1) Where an application has been made to the regulatory authority for a licence, or recognition of a licence or marketing authorisation under this Part, the regulatory authority, before determining the application, may request the applicant to provide it with such information relating to the application as the regulatory authority may require; and, where any such request has been made, the regulatory authority shall not be required to determine the application until either -

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

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

(2) The regulatory authority may serve on the holder of a licence, recognised licence or recognised marketing authorisation under this Part, or of an animal test certificate, a notice requiring him, within such time as may be specified in the notice, to furnish to the regulatory authority information of any description specified in the notice in accordance with the following provisions.

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

(4) Before the end of the period of two years from the date on which a marketing authorisation is recognised the holder of the recognition of that marketing authorisation shall, in respect of each description of medicinal products to

which the recognition relates which is effectively on the market in the Bailiwick within that period, notify to the regulatory authority a date on which medicinal products of that description were effectively on that market.

Offences under Part II

21. (1) Subject to section 22 (Special defences under section 21), any person who contravenes any of the provisions of sections 7 (General provisions as to dealing with medicinal products), 8 (Provisions as to manufacture and wholesale dealing) or who is in possession of any medicinal product 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 medicinal product is imported in contravention of section 7, any person who, otherwise than for the purpose of performing or exercising a duty or power imposed or conferred by or under this Law or any other enactment, is in possession of the product knowing or having reasonable cause to suspect that it was so imported shall be guilty of an offence.

(3) Any person who, being the holder of a recognised marketing authorisation, procures another person to carry out a process in the manufacture or assembly of medicinal products of a description to which the recognition relates, and -

(a) does not communicate to that person the provisions of the recognition 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 regulatory 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 recognition of any marketing authorisation, sells or supplies a substance or article to which the recognition 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 recognition which relate to the incorporation of that substance or article or any instructions required by the recognition of any authorisation 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 recognition of any marketing authorisation as are mentioned in subsection (4) are varied by the regulatory authority, and on varying those provisions the regulatory authority serve on the holder of the recognition 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 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 20 (Provision of information to regulatory authority) 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 20(2) shall be guilty of an offence.

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

(a) on summary conviction, to a fine not exceeding level 3 on the uniform scale, or

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

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

Special defences under section 21.

22. (1) Where the holder of a recognised marketing authorisation is charged with an offence under section 21 (Offences under Part II) in respect of any substance or article which has been manufactured (or, in the case of a medicinal product, manufactured or assembled) to his order by another person and has been so manufactured or assembled as not to comply with the provisions of that licence which are applicable to it, it shall be a defence for him to prove -

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

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

(2) Where the holder of a manufacturer's licence or recognised licence is charged with an offence under the section 21 in respect of any medicinal products which have been manufactured or assembled by him, in circumstances where he is not the holder of a recognised marketing authorisation 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 recognised marketing authorisation applicable to those products applicable to them, and

(b) that the products were manufactured or assembled in accordance with that recognised marketing authorisation.

Standard provisions for licences, recognition or certificate.

23. (1) The Department may by regulations prescribe standard provisions for the purposes of this Part, 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 regulatory authority in any licence, or recognition of any licence or marketing authorisation under this Part, issued or recognised 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 powers conferred on the regulatory authority in this Part, to vary the provisions of a licence, recognition 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, recognition or certificate.

Postponement of restrictions in relation to exports.

24. (1) Notwithstanding anything in sections 7 (General provisions as to dealing with medicinal products) to 23 (Standard provisions for licence or

certificate) or in Schedule 2, but subject to sections 25 (Special provisions in respect of exporting certain products) and 26 (Special provisions in respect of exporting certain products to EEA states), in relation to anything done before such day (subsequent to the first appointed day) as the Department may by order appoint for the purposes of this subsection (in this section referred to as "**the special appointed day**") those sections shall have effect as if in them -

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

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

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

(2) The Department shall not make an order under subsection (1) unless it appears to them to be necessary or expedient to do so for the purpose of giving effect to an agreement to which the Bailiwick is a party or to which it is subject, will be a party or will be subject, on the day appointed by the order.

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

(a) substantial quantities of medicinal products of that description (that is to say, quantities exceeding those

required for distribution as samples) were exported or procured to be exported during the period of twenty-four months ending immediately before the special appointed day, and

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

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

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

(b) section 17 (Termination of transitional exemptions), shall have effect in relation to paragraph (a) as it has effect in relation to the subsections of section 16 (Transitional exemptions), mentioned in that section.

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

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

(b) it authorised him to do so subject to the like provisions as are specified in the licence in relation to selling or (as the case may be) procuring the sale, or procuring the manufacture or assembly for sale, of such products;

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

(6) Where on an application for a recognised marketing authorisation made before such date as may be appointed by the order for the purposes of this subsection, which states that it is an application made by virtue of this subsection, it is proved to the reasonable satisfaction of the regulatory authority that the applicant fulfilled or will fulfil the relevant transitional conditions in relation to one or more descriptions of medicinal products, then (subject to subsection (7)) he shall be entitled to recognition of his marketing authorisation so as -

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

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

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

(7) An order made under subsection (1) may contain such provisions relating to proceedings on an application made under subsection (6) as the Department may consider appropriate.

Special provisions in respect of exporting certain products.

25. (1) Nothing in section 24(1) (Postponement of restrictions in relation to exports), shall affect the operation of any of the provisions of sections 7 (General provisions as to dealing with medicinal products) to 23 (Standard provisions for licence or certificate) or Schedule 2, in relation to any medicinal product falling within a class specified in an order made under this section by the Department.

(2) An order shall only be made under this section where it appears to the Department making the order to be requisite to do so for securing that any exemption conferred by section 24(1) does not apply to medicinal products consisting wholly or partly of substances the purity or potency of which cannot, in their opinion, be adequately tested by chemical means.

(3) Sections 24(3) to (7) (Postponement of restrictions in relation to exports), shall not have effect in relation to medicinal products of any description falling within a class specified in an order under this section which is in force

immediately before the day appointed for the purposes of subsection (1) of that section.

Special provisions in respect of exporting certain products to EEA States.

26. Nothing in section 24 (Postponement of restrictions in relation to exports), affects the operation of section 8(8) (Provisions as to manufacture and wholesale dealing), in relation to the exportation of a product, or the sale or supply of a product which involves, or is for the purposes of, the exportation of the product if -

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

(b) the exportation is, or is to be, to an EEA State.

Certificates for exporters of medicinal products.

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

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

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

(c) to the provisions of any regulations made under paragraph 12 of Schedule 2 in respect of clinical trials and to any authorisation, recognition or other thing done by virtue of those regulations.

PART III
FURTHER PROVISIONS RELATING TO DEALINGS WITH MEDICINAL PRODUCTS

Provisions as to sale or supply of medicinal products

General sale lists.

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

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

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

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

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

(a) that person is, in respect of that business, a person lawfully conducting a retail pharmacy business, or, if that person is conducting pharmacy related business in Sark, is otherwise authorised by the regulatory authority,

(b) the product is sold, offered or exposed for sale, or supplied, on premises which are a registered pharmacy or, if in Sark, on premises which have been authorised in writing by the regulatory authority, 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.

Sale or supply of medicinal products on general sale list.

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

(2) The place at which the medicinal product is sold, offered, exposed or supplied as mentioned in the preceding subsection must be premises of which the person carrying on the business in question is the occupier and which he is able to close so as to exclude the public, unless the product is sold, offered, exposed for sale or supplied by means of an automatic machine and the product is a medicinal product in the automatic machines section of a general sale list.

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

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

Sale of medicinal products from automatic machines.

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

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

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

Exemptions from sections 29 and 30

Exemptions for doctors and dentists.

32. (1) The restrictions imposed by sections 29 (Sale or supply of medicinal products not on general sale list) and 30 (Sale or supply of medicinal products on general sale list), do not apply to the sale, offer for sale, or supply of a medicinal product -

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

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

(c) in Sark, in the course of business conducted at premises which have been authorised in accordance with section 29.

(2) Those restrictions also do not apply -

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

(b) to the sale or supply of a medicinal product of a description, or falling within a class, specified in an order made by the Department for the purposes of this paragraph, where the product either is sold or supplied by a registered midwife in the course of her professional practice or is delivered or administered by such a midwife on being supplied in pursuance of any arrangements made by the Department.

Exemptions in respect of herbal remedies.

33. (1) Subject to the following provisions, the restrictions imposed by sections 29 (Sale or supply of medicinal products not on general sale list) and 30 (Sale or supply of medicinal products on general sale list), do not apply to anything done at premises of which the person carrying on the business in question is the occupier and which he is able to close so as to exclude the public, and which consists of the sale, or offer or exposure for sale, or the supply in circumstances corresponding to retail sale, of a herbal remedy where the processes to which the plant or plants are subjected consist of drying, crushing or comminuting, with or without any subsequent process of tabletting, pill-making, compressing or diluting with water, but not any other process.

(2) Without prejudice to subsection (1), those restrictions do not apply to the sale or supply of a herbal remedy where the person selling or supplying the remedy sells or supplies it for administration to a particular person after being requested by or on behalf of that person and in that person's presence to use his own judgment as to the treatment required.

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

(4) The Department may, by order, specify other circumstances in which these restrictions shall not apply.

Power to extend or modify exemptions.

34. (1) The Department may by order provide that either or both section 29 (Sale or supply of medicinal products not on general sale list) or 30 (Sale or supply of medicinal products on general sale list) shall have effect, subject to such exemptions (other than those for the time being having effect by virtue of sections 32 (Exemptions for doctors and dentists) and 33 (Exemptions in respect of

herbal remedies) and Part VII (Veterinary medicinal products and veterinary surgeons)) as may be specified in the order.

(2) Any exemption conferred by an order under subsection (1) may be conferred subject to such conditions or limitations as may be specified in the order.

(3) The Department may by order provide that section 32(1)(b) or 32(2) (Exemptions for doctors and dentists) or Part VII (Veterinary medicinal products and veterinary surgeons), shall cease to have effect, or shall have effect subject to such exceptions or modifications as may be specified in the order.

Additional provisions

Medicinal products on prescription only.

35. (1) The States may by Ordinance specify descriptions or classes of medicinal products for the purposes of this Law; and, in relation to any description or class so specified, the Ordinance shall state which of the following -

(a) doctors,

(b) dentists,

(c) veterinary surgeons,

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

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

are to be appropriate practitioners for the purposes of this Law.

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

(a) persons who are registered in the register maintained under section 3 of the Registered Health Professionals Ordinance, 2006[j],

(b) persons whose names are entered in a register maintained by the Health and Social Services Department under section 2 of the Doctors, Dentists and Pharmacists Ordinance, 1987[k],

(c) persons who are registered in either of the registers of ophthalmic opticians kept under section 7(1) of the Opticians Act 1989[l],

(d) persons who are registered in any register established, continued or maintained under an Order in Council under section 60(1) of the Health Act 1999[m], and

(e) any other description of persons which appears to the States to be a description of persons whose profession

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[j] Ordinance No. III of 2006.

[k] Ordinance No. XIII of 1987, amended by XXXIV of 1987 and applied in Alderney by Ordinance No. IV of 1988.

[l] An Act of Parliament (1989 c.44).

[m] An Act of Parliament (1999 c.8).

is regulated by or under a provision of any enactment and which the States considers it appropriate to specify.

(3) Where an Ordinance under this section includes provision by virtue of subsection (1)(e), the Ordinance shall specify such conditions as are necessary to secure that any person who is an appropriate practitioner by virtue of the provision may prescribe, give directions or administer only in respect of human use.

(4) Subject to the following provisions -

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

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

(5) Subsection (4)(a) shall not apply to the sale or supply of a medicinal product -

(a) to a patient of his by a doctor or dentist who is an appropriate practitioner, or

(b) for administration to an animal or herd under his care, by a veterinary surgeon who is an appropriate practitioner.

(6) Without prejudice to subsection (3), any Ordinance made by the Department for the purposes of this section may provide -

(a) that subsection (4)(a) or (b), or both those subsections, shall have effect subject to such exemptions as may be specified in the Ordinance or, where the appropriate practitioner is a registered nurse or midwife, or is an appropriate practitioner by virtue of provision made under subsection (1)(e), such modifications as may be so specified, and

(b) that, for the purpose of subsection 4(a), a medicinal product shall not be taken to be sold or supplied in accordance with a prescription given by an appropriate practitioner unless such conditions as are prescribed by the Ordinance are fulfilled.

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

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

(b) administer any such medicinal product, or

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

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

(8) An Ordinance under this section may provide, in relation to any condition specified by virtue of subsection (7), for the condition to have effect subject to such exemptions as may be specified in the Ordinance.

(9) Where a condition is specified by virtue of subsection (7), any prescription or direction given by a person in contravention of the condition is not (subject to such exemptions or modifications as may be specified in the Ordinance by virtue of subsection (6)(a)) given by an appropriate practitioner for the purposes of subsection (4)(a) or (b).

(10) Any exemption conferred, or modification made by an Ordinance in accordance with subsection (6)(a) or (8) may be conferred, or made subject to such conditions or limitations as may be specified in the Ordinance.

Requirement to specify certain products for human use as prescription-only products.

36. (1) The Department shall, subject to subsection (4), exercise their powers under section 35(1) (Medicinal products on prescription only), so as to secure that every product -

(a) in respect of which a marketing authorisation is recognised,

(b) to which the 2001 Directive applies, and

(c) to which subsection (2) applies,

falls within one of the descriptions or classes specified for the purposes of section 35.

(2) This subsection applies to any product which -

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

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

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

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

(3) In considering whether subsection (2) applies to a product the Department, acting on the advice of the Committee, shall take into account whether the product -

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

(b) contains a substance which is listed in any of Schedules I to IV to the Psychotropic Substances Convention

(where the product is not a preparation which may be exempted from measures of control in accordance with paragraphs 2 and 3 of article 3 of that Convention),

(c) is likely, if incorrectly used -

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

(ii) to lead to addiction, or

(iii) to be used for illegal purposes,

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

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

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

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

(4) Subsection (1) shall not apply in relation to any product if the Department so determines, acting on the advice of the Committee having regard to -

(a) the maximum single dose,

(b) the maximum daily dose,

(c) the strength of the product,

(d) its pharmaceutical form,

(e) its packaging, or

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

(5) In this section and in Part VII (Veterinary medicinal products and veterinary surgeons) -

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

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

Special provisions in relation to new medicinal products.

37. (1) The following provisions shall have effect where an Ordinance under section 35 (Medicinal products on prescription only), is made so as

to apply to all medicinal products which fall within a class specified in the Ordinance and are of a description in respect of which the following conditions are fulfilled, that is to say, that -

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

(b) a marketing authorisation recognised under Part II, (whether before, on or after the date on which the order comes into operation) applies to medicinal products of that description (whether it also applies to medicinal products of any other description or not), and

(c) before the grant of that recognition, no marketing authorisation had been recognised which was applicable to medicinal products of that description.

(2) Where such an Ordinance is made in accordance with subsection (1) -

(a) the restrictions imposed by section 35(2), shall not apply by virtue of the Ordinance to medicinal products of any description except during a period beginning with the date which, in relation to medicinal products of that description, is the relevant date and of such duration from that date as may be specified in the Ordinance,

(b) in section 35(4)(a), the reference to exemptions specified in the Ordinance shall, in relation to that

Ordinance, be construed as including a reference to any exemption specified in a direction given by the Department and relating to medicinal products of a particular description specified in that direction.

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

Restricted sale, supply and administration of certain medicinal products.

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

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

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

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

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

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

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

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

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

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

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

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

Special restrictions on persons to be supplied with medicinal products.

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

(a) being the holder of a recognised marketing authorisation, or

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

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

Adulteration of medicinal products.

40. 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.

Protection of purchasers of medicinal products.

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

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

(3) Subsection (1) is not 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) is not contravened by reason only that a substance has been added to, or abstracted from, the medicinal product, if it is proved that -

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

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

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

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

(b) in subsection (1), for the words "demanded by the purchaser", there were substituted the words "specified in the prescription".

Compliance with standards specified in monographs in certain publications.

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

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

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

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

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

(3) Where a medicinal product is sold or supplied in the circumstances specified in subsection (1) or (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 one of the following, that is to say, the British Pharmacopoeia, the British Pharmaceutical Codex, the British Veterinary Codex, the European Pharmacopoeia and any other publication that the Department may, by order, specify,

"**the relevant monograph**" in relation to the sale or supply of a medicinal product which has been demanded, described in a prescription, or offered or exposed for sale, by or by express reference to a particular name -

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

in that edition, means the appropriate current monograph (if any) headed by that name,

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

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

"**current**" means current at the time when the medicinal product in question is demanded, described in a prescription, or offered or exposed for sale, as mentioned in subsection (1) or (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 in the current edition of the British or European Pharmacopoeia,

(b) if there is no such monograph, then the monograph (if any) headed by that name specified in any regulations made by the Department, or

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

(6) Subject to subsection (8), 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) In relation to any time on or after the date on which, by notice published in La Gazette Officiel by or on behalf of the Department, it is declared that the European Pharmacopoeia prepared in pursuance of the Convention in that behalf done at Strasbourg on 22nd July 1964 is to have effect for the purposes of

this section, subsections (1) and (2) shall have effect as if, after the words "that name is", in each place where those words occur, there were inserted the words "or is an approved synonym for," subsection (4) shall have effect as if, before the words "the British Pharmacopoeia", there were inserted the words "the European Pharmacopoeia", and after the words "headed by that name", in each place where those words occur, there were inserted the words "or by a name for which it is an approved synonym", and subsection (5) shall have effect as if for paragraph (a) of that subsection there were substituted the following paragraphs -

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

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

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

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

(b) if it is an edition previous to the current edition of that Pharmacopoeia, shall be taken as it was immediately before the time when it was superseded by a

subsequent edition of that Pharmacopoeia in force in the United Kingdom (that is to say, together with any amendments, additions and deletions made to it which, by notice so published before that time, had been declared so to have effect),

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

Further powers to regulate dealings with medicinal products.

43. (1) The Department may by regulations prescribe such requirements as they may consider necessary or expedient with respect to any of the following matters -

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

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

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

(d) the accommodation (including the amount of space) to be provided in any premises for members of the public

to whom medicinal products are sold or supplied or for whom medicinal products are being prepared or assembled,

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

(f) the safekeeping of medicinal products,

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

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

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

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

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

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

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

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

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

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

Offences, and provision for disqualification

Offences under Part III.

44. (1) The following provisions have effect subject to sections 124 (Contravention due to default of other person) and 125 (Warranty as defence).

(2) Any person who gives a prescription or directions or administers a medicinal product in contravention of a condition imposed by an Ordinance under section 35(7) (Medicinal products on prescription only) shall be guilty of an offence.

(3) Any person who -

(a) is an appropriate practitioner by virtue of provision made under section 35(1), and

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

shall be guilty of an offence.

(4) Any person who contravenes any of the following provisions of this Part, that is to say, sections 29 (Sale or supply of medicinal products not on general sale list), 35 (Medicinal products on prescription only), 40 (Adulteration of medicinal products), 41 (Protection of purchasers of medicinal products) and 42 (Compliance with standards specified in monographs in certain publications), or who contravenes any regulations made under section 38 (Restricted sale, supply and administration of certain medicinal products) shall be guilty of an offence.

(5) A person who has in his possession a medicinal product to which section 35(2)(a) applies, with the intention of supplying it otherwise than in accordance with the requirements of that paragraph, shall be guilty of an offence.

(6) Any person guilty of an offence under subsection (2), (3), (4), or (5) shall be liable -

(a) on summary conviction, to a fine not exceeding level 3 on the uniform scale,

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

(7) Any person who contravenes section 30 (Sale or supply of medicinal products on general sale list) or 31(1) (Sale of medicinal products from automatic machines) or an order made under section 31(2), shall be guilty of an

offence and liable on summary conviction to a fine not exceeding level 3 on the uniform scale.

(8) Any regulations made under section 43 (Further powers to regulate dealings with medicinal products), may provide that any person who contravenes the regulations shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the uniform scale or such lesser sum as may be specified in the regulations.

Disqualification on conviction of certain offences.

45. (1) Where in any proceedings a person is convicted of an offence under section 44(6) (Offences under Part III), in respect of any premises used for carrying on a retail pharmacy business, then, upon an application being made by Her Majesty's Procureur, the court by or before which he was convicted may (subject to the following provisions) make an order disqualifying him from using those premises for the purposes of such a business for such period, not exceeding two years, as may be specified in the order.

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

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

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

(c) to any offences under section 44(6), of which he has previously been convicted.

(3) No order under this section shall be made against a person on the application of Her Majesty's Procureur unless that person has, not less than

fourteen days before the date of the hearing, been given notice in writing of the intention to apply for such an order.

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

(5) Subject to subsection (6), at any time after the end of the period of six months from the date on which an order under this section comes into force, the person to whom the order relates may apply to the court by which the order was made to revoke the order or to vary it by reducing the period of disqualification.

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

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

PART IV
PHARMACIES

Appointment of registrar.

46. The Department shall appoint an appropriate person as registrar for the purposes of this Part.

Persons lawfully conducting retail pharmacy business

General provisions.

47. (1) Subject to the provisions of any order made under section 54 (Power to extend or modify conditions), a person carrying on a retail pharmacy business shall be taken to be a person lawfully conducting such a business if, not being disqualified by virtue of section 61 (Power for the Department to direct removal from register and for relevant disciplinary committee to disqualify) -

(a) that person is a pharmacist and the conditions specified in section 50 (Business carried on by pharmacist in person), are fulfilled in relation to the business,

(b) that person is a body corporate and the conditions specified in section 51 (Business carried on by body corporate), are fulfilled in relation to the business, or

(c) that person is a representative of a pharmacist (as defined by section 52 (Representative of pharmacist in case of death or disability)) and the conditions specified in section 52(2) of that section are fulfilled in relation to him and in relation to the business and the period applicable in accordance with section 52(3) has not expired.

(2) For the purposes of the application of this Part of this Law to a business which -

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

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

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

(3) In this Part -

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

"**the pharmacy registrar**" in relation to the Bailiwick means the person appointed by the Department to act as registrar under section 46 (Appointment of registrar).

Prohibition notice.

48. (1) Where the Chief Pharmacist considers that a pharmacist is not competent to practise, for whatever reason, he shall notify the Department of his opinion and shall request the Department to serve a notice in writing on that pharmacist, prohibiting him from working for a specified period.

(2) Where the Department receives a request from the Chief Pharmacist under subsection (1), it shall serve a notice on the relevant pharmacist as soon as is reasonably practicable.

(3) A notice served under subsection (2) shall specify a period which shall not exceed 48 hours.

(4) Before a notice is given to a person by the Department under this section, the person must be given a reasonable opportunity to prove that they are competent to practise unless the Department believes that the situation is so serious as to merit immediate service of the notice.

(5) A person who without reasonable excuse fails to comply with a notice served under this section is guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the uniform scale.

Service of notice.

49. A notice served by the Department under section 48 (Prohibition notice) shall be validly served, or deemed to be validly served, for the purposes, if the notice -

(a) is handed to the pharmacist, or

(b) is handed to an appropriate person at the pharmacist's registered premises who undertakes to bring the document to the immediate attention of the pharmacist.

Business carried on by pharmacist in person.

50. The conditions referred to in section 47(1)(a) (General provisions), are that, at all premises where the business is carried on and medicinal products, other than medicinal products on a general sale list, are sold by retail -

(a) the business, so far as concerns the retail sale at those premises of medicinal products (whether they are medicinal products on a general sale list or not), or the supply at those premises of such products in circumstances corresponding to retail sale, is under the personal control of the person carrying on the business or that of another pharmacist, and

(b) his name and certificate of registration or those of the other pharmacist, as the case may be, are conspicuously exhibited,

and that it is the personal control of persons who are recognised pharmacists by virtue of the Doctors, Dentists and Pharmacists Ordinance, 1987, which fulfils the condition imposed by virtue of paragraph (a) in relation to such of those premises in the Bailiwick as have been registered pharmacies for less than three years.

Business carried on by body corporate.

51. (1) The conditions referred to in section 47(1)(b) (General provisions), are that the business, so far as concerns the keeping, preparing and dispensing of medicinal products other than medicinal products on a general sale list, is under the management of a superintendent in respect of whom the requirements specified in subsection (2) are fulfilled, and that, at all premises where the business is carried on and medicinal products, other than medicinal products on a general sale list, are sold by retail -

(a) the business, so far as concerns the retail sale at those premises of medicinal products (whether they are medicinal products on a general sale list or not) or the supply at those premises of such products in circumstances corresponding to retail sale, if it is not under the personal control of the superintendent, is carried on, subject to the directions of the superintendent, under the personal control of a manager or assistant who is a pharmacist, and

(b) the name and certificate of registration of the person under whose personal control the business is carried on at those premises as mentioned in the preceding

paragraph (whether he is the superintendent or some other person) are conspicuously exhibited,

and that it is the personal control of persons who (whether the superintendent or a manager or assistant) are recognised pharmacists by virtue of the Doctors, Dentists and Pharmacists Ordinance 1987 in relation to such of those premises in the Bailiwick as have been registered pharmacies for less than three years.

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

(a) the superintendent is a pharmacist who is resident in the Bailiwick,

(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 Department, and

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

Representative of pharmacist in case of death or disability.

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

(a) he dies,

(b) a declaration of insolvency has been made against him or his affairs have been declared in a state of "désastre" at a meeting of arresting creditors held before a Commissioner of the Royal Court, the Court

of Alderney or the Court of the Seneschal,

(c) an interim vesting order has been made against him in respect of any real property in the Bailiwick,

(d) otherwise than for the sole purpose of solvent amalgamation, solvent reconstruction or solvent winding-up, a liquidator (provisional or otherwise) has been appointed to act in relation to his estate or affairs, or

(e) he becomes a person who lacks capacity to carry on the business.

(2) In subsection (1)(e), the reference to a person who lacks capacity to carry on the business includes a person for whom a guardian has been appointed by the Royal Court and in relation to whom the guardian has power for the purposes of this Part.

(3) The conditions referred to in section 47(1)(c) (General provisions), are that the name and address of the representative, and the name of the pharmacist whose representative he is, have been notified to the Department and that, at all premises at which the business is carried on and medicinal products, other than medicinal products on a general sale list, are sold by retail, -

(a) the business, so far as concerns the retail sale at those premises of medicinal products (whether they are medicinal products on a general sale list or not) or the supply at those premises of such products in circumstances corresponding to retail sale, is under the personal control of a pharmacist, and

(b) his name and certificate of registration are conspicuously exhibited.

(4) The period referred to in section 47(1)(c) -

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

(b) in the case of a declaration of insolvency or where the pharmacist's affairs have been declared in a state of "désastre" is a period of three years from the date of any such declaration,

(c) in the case where an interim vesting order has been made against him in respect of any real property in the Bailiwick is a period of three years from the date of the interim vesting order, and

(d) in a case falling within subsection (1)(d) or (2), is a period of three years from the date of the appointment of the liquidator or guardian,

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

(5) In this section "**representative**" -

(a) in relation to a pharmacist who has died, means his executor or administrator and, in respect of a period of three months from the date of his death, if he has died leaving no executor who is entitled and willing to carry

on the business, includes any person beneficially interested in his estate,

(b) in a case falling within subsection (1)(a) to (d), means the Sheriff or any liquidator appointed, and

(c) in a case falling within subsection (2), means the guardian.

A responsible pharmacist.

53. The Department may make regulations prescribing conditions which must be satisfied by a responsible pharmacist whilst in control of the premises where the business is carried on and such regulations may, without limitation, prescribe conditions relating to -

(a) the retail supply of medicinal products (whether they are on a general sale list or not),

(b) the supply at those premises of medicinal products, and

(c) the safe and effective running of the pharmacy business at the premises in question.

Power to extend or modify conditions.

54. (1) The Department may by order add to, revoke or vary any of the provisions of sections 50 (Business carried on by pharmacist in person) to 52 (Representative of pharmacist in case of death or disability), so as either -

(a) to modify, or provide new conditions in substitution for, the conditions referred to in any of the paragraphs of section 47(1) (General provisions), or

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

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

(3) Any order made under this section may direct that section 47(1) or (2) shall have effect subject to such exceptions or modifications as appears to the Department to be necessary or expedient in consequence of the provision made by the order in accordance with subsection (1).

(4) Where an order under this section is for the time being in force, any reference to section 47 of this Law in any other enactment as amended by this Law shall be construed as a reference to that section as modified by the order.

Registration of pharmacies

Meaning of "registered pharmacy".

55. (1) In this Law "**registered pharmacy**" means premises for the time being entered in the register required to be kept under section 56 (Registration of premises).

(2) In this section and in section 57 (Supplementary provisions as to registration of premises), "**year**" means a period of twelve months beginning on such date as the Department may from time to time determine.

Registration of premises.

56. (1) It shall be the duty of the pharmacy registrar to keep a register for the purposes of this Law (in this Law referred to as "**the register**") and, subject to the following provisions, on payment of the prescribed fee to enter in the register any premises in respect of which an application is made under this section.

(2) Any application for the registration of premises under this section shall be made in the prescribed manner and shall specify the premises to which the application relates and shall contain such other particulars as may be prescribed.

(3) On the making of any such application the pharmacy registrar shall notify the Department, specifying the premises to which the application relates and the date on which the application was made, and shall not enter those premises in the register before the end of the period of two months from that date, unless before the end of that period the Department consents to his doing so.

(4) If it appears to the Department that in a material respect the premises do not comply with the requirements of regulations made under section 43 (Further powers to regulate dealings with medicinal products) which are for the time being in force and accordingly it proposes to certify that the premises are unsuitable for registration under this section, it shall, before the end of the period referred to in subsection (3), serve on the applicant a notice stating its proposals and the reasons for them, and shall serve a copy of that notice on the pharmacy registrar; and, where a copy of such a notice is served on him, the pharmacy registrar shall not enter the premises in the register except where required to do so in accordance with the following provisions.

(5) If, within the time allowed after the service on him of a notice under subsection (4), the applicant gives notice to the Department of his desire to be heard with respect to the proposals, or makes representations in writing to the

Department with respect to the proposals, then, before determining whether to issue a certificate under this section in respect of the premises -

(a) if the applicant has given notice of his desire to be heard, the Department shall give him an opportunity of appearing before, and being heard by, a person appointed by that Department for the purpose, or

(b) if he has made representations in writing, the Department shall consider those representations.

(6) Where the Department has served a notice under subsection (4), then -

(a) if it determines not to issue a certificate certifying that the premises are unsuitable for registration under this section, it shall notify the applicant and the pharmacy registrar of its decision and (subject to subsection (7)) the pharmacy registrar shall immediately enter the premises in the register,

(b) if the Department issues such a certificate, it shall transmit the certificate to the pharmacy registrar and shall notify the applicant that it has done so, and, if so required by the applicant, shall inform him of the reasons for his decision to issue such a certificate.

(7) Notwithstanding anything in the preceding provisions, the pharmacy registrar shall not enter any premises in the register in pursuance of an application under this section unless it is shown to his reasonable satisfaction either -

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

(b) that, if the premises are entered in the register, and the applicant begins to carry on a retail pharmacy business at those premises, then as from the time when he begins to do so he will be a person lawfully conducting a retail pharmacy business.

(8) In this section "**the time allowed**" means the period of twenty-eight days or such extended period as the Department may in any particular case allow.

Supplementary provisions as to registration of premises.

57. (1) The Department may make regulations in respect of any premises entered on the register.

(2) Regulations under subsection (1) may, without limitation, provide for -

(a) a fee to be paid in respect of retaining those premises on the register,

(b) for the pharmacy registrar to remove any premises from the register where no fee is paid within any time as may be specified for payment,

(c) for the pharmacy registrar to restore any premises to the register in accordance with any conditions which the Department shall specify,

(d) for the registration of the premises to become void in certain circumstances such as a change of ownership of the premises, and

(e) for applicants to be able to apply for restoration of the premises in certain circumstances as shall be prescribed.

Annual return of premises to registrar.

58. Every person who carries on a retail pharmacy business shall, in the month of January in each year, or such other month as the Department may prescribe by order, send to the pharmacy 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) in the case of any premises where medicinal products, other than medicinal products on a general sale list, are sold by retail, or are supplied in circumstances corresponding to retail sale, the name of the pharmacist under whose personal control the business, so far as concerns the retail sale or supply of medicinal products at those premises, is carried on.

Provisions as to use of certain titles, descriptions and emblems

Restrictions on use of titles, descriptions and emblems.

59. (1) The following provisions have effect subject to section 60 (Provisions for modifying or extending restrictions under section 59).

(2) No person shall -

(a) take or use any of the following titles, that is to say, chemist and druggist, druggist, dispensing chemist, and dispensing druggist, or

(b) take or use the title of chemist in connection with the sale of any goods by retail or the supply of any goods in circumstances corresponding to retail sale,

unless the conditions specified in the next following subsection are fulfilled.

(3) Those conditions are -

(a) in the case of an individual, that he is a person lawfully conducting a retail pharmacy business (either alone or as a member of a partnership) and that he does not take or use the title in question in connection with any premises at which any goods are sold by retail, or are supplied in circumstances corresponding to retail sale, unless those premises are a registered pharmacy, and

(b) in the case of a body corporate, that the body is a person lawfully conducting a retail pharmacy business and that the title in question is not taken or used by that body in connection with any premises at which any goods are sold by retail, or are supplied in circumstances corresponding to retail sale, unless those premises are a registered pharmacy, and that the pharmacist who, in relation to that business, is such a superintendent as is referred to in section 51(1)

(business carried on by body corporate), is a member of the board of the body corporate.

(4) No person shall, in connection with a business carried on by him which consists of or includes the retail sale of any goods, or the supply of any goods in circumstances corresponding to retail sale, use the description "pharmacy" except in respect of an approved pharmacy or in respect of the pharmaceutical department of a hospital.

(5) No person who is not a pharmacist shall -

(a) take or use any of the following titles, that is to say, pharmaceutical chemist, pharmaceutist, pharmacist, member of the Royal Pharmaceutical Society, and Fellow of the Royal Pharmaceutical Society and Pharmaceutical Society of Northern Ireland, and

(b) without prejudice to the preceding paragraph, 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 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 (6) the use of the description "**pharmacy**", in connection with a business carried on at any premises, shall be taken to be likely to suggest that the person carrying on the business (where that person is not a body corporate) is a pharmacist and that any other person, under whose personal control the business (so far as concerns the retail sale of medicinal products or the supply of such products in circumstances corresponding to retail sale) is carried on at those premises, is also a pharmacist.

(8) Where a person is lawfully conducting a retail pharmacy business as being a representative of a pharmacist in the circumstances specified in section 47(1)(c) (General provisions), subsections (5) 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.

Provision for modifying or extending restrictions under section 59.

60. (1) The Department may by order provide that any of the restrictions imposed by section 59 (Restrictions on use of titles, descriptions and emblems), shall cease to have effect, or shall have effect subject to such exceptions as may be specified in the order.

(2) Without prejudice to subsection (1), regulations made by the Department may (in addition to the restrictions for the time being having effect by virtue of section 59) impose such further restrictions or other requirements with respect to the use of titles, descriptions and emblems as may be specified in the regulations.

(3) Without prejudice to the application of section 132 (Ordinances, orders and regulations), before making any order or regulations under this section the Department shall consult the Chief Pharmacist.

Disqualification and removal of premises from register

Power for the Department to direct removal from register and for relevant disciplinary committee to disqualify.

61. (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 Laws, 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, acting on the advice of the Chief Inspector 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 -

(i) that the body corporate shall be removed from the register for the purposes of this Part, and

(ii) that the relevant disciplinary committee should be invited to consider whether that body should be disqualified from practising in the UK for the purposes of this Part,

and if the relevant disciplinary committee consider that the body should be disqualified from practising in the United Kingdom for the purposes of this Part and do so disqualify it, then the body corporate shall be removed from the register.

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

(a) if the Department gives a direction under subparagraph (i) of that subsection, the pharmacy registrar may remove from the register all premises entered in the register as being premises at which the body corporate carries on a retail pharmacy business, or such of them as may be specified in the direction under that subparagraph, and

(b) if the Department gives a direction under subparagraph (ii) and the relevant disciplinary committee consider that the body should be disqualified from practising in the UK for the purposes of this Part and do so disqualify it, the pharmacy registrar shall remove from the register all those premises, or such of them as may be specified in the direction under that subparagraph.

(3) Directions under subsection (1), may, if the Department thinks fit, be given so as to have effect for a limited period; and in that case the pharmacy 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 (1).

(4) Where, in any such case as is mentioned in section 52(1) (Representative of pharmacist in case of death or disability), a representative, or a person employed by a representative in the business referred to in that subsection -

(a) is convicted of an offence, or

(b) has been guilty of misconduct,

and the offence or misconduct is such as in the opinion of the 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 and taking advice from the Chief Inspector, may direct -

(i) that the representative shall be removed from the register for the purposes of this Part, and

(ii) that the relevant disciplinary committee should be invited to consider whether that representative, if he is a pharmacist, should be disqualified from practising in the United Kingdom for the purposes of this Part, and

(iii) if the relevant disciplinary committee consider that the representative should be disqualified from practising in the UK for the purposes of this Part and do so disqualify him, that the representative shall be removed from the register.

(5) In this and the next section -

"**the relevant Laws**" means this Law and the Misuse of Drugs (Bailiwick of Guernsey) Law, 1974, as amended[n],

"**representative**" has the same meaning as in section 52, and

"**relevant disciplinary committee**" means -

(a) in relation to Great Britain, the disciplinary committee established under Article 7(1)(b) of the Pharmacists and Pharmacy Technicians Order, 2007[o], and

(b) in relation to Northern Ireland, the Statutory Committee appointed under Article 19 of the Pharmacy (Northern Ireland) Order, 1976[p].

Grounds for removal from the register or disqualification in certain cases.

62. The Department shall not give a direction under section 61(1) (Power for the Department to direct removal from register and for relevant disciplinary committee to disqualify), in a case falling within paragraph (b) of that provision, and shall not give a direction under section 61(4), unless -

(a) 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) in the case of a body corporate, a member of the board, or an officer of or person employed by the body

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[n] Ordres en Conseil, Vol. XXIV, p. 273; Vol. XXVIII, P. 307; Vol. XXX1, p.47; No. XIII of 1991; No. V of 1992; No. XVI of 1995 and No. III of 2000; No IV of 2006 and Recueil d'Ordonnances Tome No. IX, p.270

[o] UK SI 2007 No. 289

[p] UK SI 1976 No. 1213 (N.I.22).

corporate, had, at some time within twelve months before the date on which the offence or misconduct in question occurred, been guilty of a similar offence or similar misconduct and that the board had, or with the exercise of reasonable care would have had, knowledge of that previous offence or misconduct,

(c) in the case of the representative, he or a person employed by him had, at some time within twelve months before the date on which the offence or misconduct in question occurred, been guilty of a similar offence or similar misconduct and (where it was a similar offence or similar misconduct on the part of an employee) 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, the board, or the representative, had, or with the exercise of reasonable care would have had, knowledge of its continuance, or

(e) in the case of an offence in respect of a contravention of an enactment contained in any of the relevant Laws, the board, or the representative, had not exercised reasonable care to secure that the enactment was complied with.

Procedure relating to removal from the register or disqualification.

63. (1) The Department, shall not give a direction under section 61 (Power for the Department to direct removal from the register and for relevant disciplinary committee to disqualify), until the end of the period of three months

from the date on which notice of the direction is given to the body corporate or other person to whom it relates, and, if an appeal against the direction is brought under this section, the direction shall not take effect 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 three months specified in subsection (1), appeal against the direction to the Royal Court.

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

(4) An appeal from a decision of the Royal Court on a point of law lies, with leave of the Royal Court or Court of Appeal, to the Court of Appeal.

Reinstatement to register and revocation of disqualification.

64. (1) At any time while a direction under section 61 (Power for the Department to direct removal from the register and for relevant disciplinary committee to disqualify), is in force -

(a) the Department, either on the application of the person to whom it relates or without any such application, may reinstate the person to the register,

(b) the Department may invite the relevant disciplinary committee either on the application of the person to whom it relates or without any such application, to revoke any disqualification, and

(c) if the relevant disciplinary committee considers that the disqualification should be revoked for the purposes of this Part, then the Department may reinstate the person to the register.

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

(3) Sections 63(2) to (4) (Procedure relating to removal from the register or disqualification) shall have effect in relation to any appeal under this section as they have effect in relation to appeals under that section.

Offences under Part IV.

65. (1) Any person who contravenes section 58 (Annual return of premises to pharmacy registrar), shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 3 on the uniform scale.

(2) Any person who contravenes section 59 (Restrictions on use of titles, descriptions, or emblems), or who contravenes any regulations made under section 60(2) (Provisions for modifying or extending restrictions under section 59), shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 3 on the uniform scale.

PART V
CONTAINERS, PACKAGES AND IDENTIFICATION OF MEDICINAL PRODUCTS

Labelling and marking of containers and packages.

66. (1) The Department may make regulations imposing such requirements as, for any of the purposes specified in subsection (2), it considers necessary or expedient with respect to any of the following matters, that is to say -

(a) the labelling of containers of medicinal products,

(b) the labelling of packages of medicinal products,

(c) the display of distinctive marks on containers and packages of medicinal products.

(2) The purposes referred to in subsection (1) 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) complying with any provision of any enactment that the Department considers to be relevant.

(3) No person shall, in the course of a business carried on by him, sell or supply, or have in his possession for the purpose of sale or supply, any medicinal product in such circumstances as to contravene any requirements imposed by regulations under this section which are applicable to that product.

(4) In so far as any such requirements relate to the labelling or marking of containers of medicinal products, a person who, in the course of a business carried on by him, sells or supplies a medicinal product to which the requirements are applicable without its being enclosed in a container shall, except in so far as the regulations otherwise provide, be taken to contravene those requirements as if he had sold or supplied it in a container not complying with those requirements.

(5) Without prejudice to the preceding provisions, 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.

Leaflets.

67. (1) The Department may make regulations imposing such requirements as, for any of the purposes specified in section 66(2) (Labelling and marking of containers and packages), it considers necessary or expedient with respect to leaflets relating to medicinal products which are supplied, or are intended to be supplied, with the products, whether by being enclosed in containers or packages of the products or otherwise.

(2) No person shall, in the course of a business carried on by him, supply with any medicinal product, or have in his possession for the purpose of so supplying, a leaflet which contravenes any requirements imposed by regulations under this section which are applicable to that leaflet.

(3) Without prejudice to the preceding provisions, no person shall, in the course of a business carried on by him, supply with a medicinal product of any description, or have in his possession for the purpose of so supplying, a leaflet which -

(a) falsely describes the product, or

(b) is likely to mislead as to the nature or quality of the product or as to the uses or effects of medicinal products of that description.

(4) No person shall, in the course of a business carried on by him, supply a product to which the 2001 Directive applies, unless -

(a) a leaflet enclosed in, or supplied with, the container or package of the product, or

(b) the container or package itself,

complies with the provisions of any regulations made under subsection (1).

Requirements as to containers.

68. (1) The Department may make regulations prohibiting the sale or supply of medicinal products otherwise than in containers which comply with such requirements as the Department considers necessary or expedient for any of the purposes specified in section 66(2) (Labelling and marking of containers and packages), or for the purpose of preserving the quality of the products, and in particular, may by the regulations require such containers to be of such strength, to be made of such materials, and to be of such shapes or patterns, as may be prescribed.

(2) No person shall, in the course of a business carried on by him, sell or supply, or have in his possession for the purpose of sale or supply, any medicinal product in such circumstances as to contravene any requirements imposed by regulations under this section which are applicable to that product.

Distinctive colours, shapes and markings of medicinal products.

69. (1) Regulations made by the Department may impose such requirements as, for any of the purposes specified in section 66(2) (Labelling and marking of containers and packages), that the Department considers necessary or expedient with respect to any one or more of the following matters, that is to say -

(a) the colour of the products,

(b) the shape of the products, and

(c) distinctive marks to be displayed on the products.

(2) Regulations made under this section may provide that medicinal products of any such description, or falling within any such class, as may be specified in the regulations shall not except in such circumstances (if any) as may be so specified, be of any such colour or shape, or display any such mark, as may be so specified.

(3) No person shall, in the course of a business carried on by him, sell or supply, or have in his possession for the purpose of sale or supply, any medicinal product which contravenes any requirements imposed by regulations under this section.

Display of information on automatic machines.

70. (1) Regulations made by the Department may impose such requirements as they consider necessary or expedient with respect to the display on

automatic machines of information relating to medicinal products offered or exposed for sale by means of such machines.

(2) No person shall offer or expose for sale any medicinal product by means of an automatic machine in such circumstances as to contravene any requirements imposed by regulations under this section which are applicable to that product.

Offences under Part V and supplementary provisions.

71. (1) Subject to sections 124 (Contravention due to default of other person) and 125 (Warranty as defence) any person who contravenes the provisions of section 66(5) (Labelling and marking of containers and packages) or 67(3) or (4) (Leaflets) shall be guilty of an offence and liable -

(a) on summary conviction, to a fine not exceeding level 3 on the uniform scale,

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

(2) Any regulations made under this Part, may provide that any person who contravenes the regulations, or who contravenes the provisions of section 66(3), 67(2), or 68(2) (Requirements as to containers), shall be guilty of an offence and -

(a) shall be liable on summary conviction to a fine not exceeding level 3 on the uniform scale or such lesser sum as may be specified in the regulations, and

(b) if the regulations so provide, shall be liable on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both.

(3) Without prejudice to the application of section 132 (Ordinances, orders and regulations), any power to make regulations conferred by sections 66 to 68 may be exercised so as to impose requirements either -

(a) in relation to medicinal products generally, or

(b) in relation to medicinal products of a particular description, or falling within a particular class, specified in the regulations.

(4) In this Part, "**requirements**" includes restrictions.

PART VI
PROMOTION OF SALES OF MEDICINAL PRODUCTS

Scope of Part VI.

72. (1) Subject to the following provisions in this Part, "**advertisement**" includes every form of advertising, whether in a publication, or by the display of any notice, or by means of any catalogue, price list, letter (whether circular or addressed to a particular person) or other document, or by words inscribed on any article, or by means of a photograph, film, sound recording or broadcast, or in any other way, and any reference to the issue of an advertisement shall be construed accordingly.

(2) Notwithstanding anything in subsection (1), in this Part, "**advertisement**" does not include spoken words except -

(a) words forming part of a sound recording or film sound track, or

(b) words broadcast.

(3) Except as provided by section 75 (Powers to regulate advertisements and representations), for the purposes of this Part, neither of the following shall be taken to constitute the issue of an advertisement, that is to say -

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

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

(4) In this Part, **"commercially interested party",** in relation to medicinal products of any description, means any person who -

(a) is the holder of a licence, or recognition of a licence or marketing authorisation under Part II, which is applicable to medicinal products of that description, or

(b) not being the holder of such a licence or recognition of a licence or marketing authorisation, is a person who, in the course of a business carried on by him, is engaged, in relation to medicinal products of that description, in any such activities as are mentioned in sections 7(2) and (4) (General provisions as to dealing with medicinal products) or in sections 8(7) or (8)

(Provisions as to manufacture and wholesale dealing), or

(c) sells by retail any medicinal products of that description in the course of a business carried on by him,

and any reference to the request or consent of a commercially interested party includes a reference to any request made or consent given by a person acting on behalf of a commercially interested party; and "**relevant business**" means any business which consists of, or includes, the sale or supply of medicinal products.

(5) In this Part, "**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)(a) or (b), and any reference to making a representation shall be construed accordingly.

(6) In this section "**film**", "**sound recording**", "**broadcast**", and related expressions, have the same meaning as in Part 1 of the Copyright (Bailiwick of Guernsey) Ordinance, 2005[q].

False or misleading advertisements and representations

73. (1) Subject to the following provisions, any person who, being a commercially interested party, or at the request or with the consent of a commercially interested party, issues, or causes another person to issue, a false or misleading advertisement relating to medicinal products of any description shall be guilty of an offence.

(2) Where a licence or recognition of a licence or marketing authorisation under Part II, is in force which is applicable to medicinal products of a

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[q] Ordinance No.XIX of 2005.

particular description and, in accordance with the provisions of the licence or recognition of a licence or marketing authorisation, the purposes for which medicinal products of that description may be recommended to be used are limited to those specified in the licence or recognition of a licence or marketing authorisation then, subject to the following provisions, any person who, being a commercially interested party, or at the request or with the consent of a commercially interested party, issues, or causes another person to issue, an advertisement relating to medicinal products of that description which consists of or includes unauthorised recommendations shall be guilty of an offence.

(3) Subject to the following provisions, any person who in the course of a relevant business carried on by him, or while acting on behalf of a person carrying on such a business, makes a false or misleading representation relating to a medicinal product in connection with the sale, or offer for sale, of that product shall be guilty of an offence; and any person who, in the course of such a business or while acting on behalf of a person carrying on such a business, makes a false or misleading representation relating to medicinal products of a particular description -

(a) to a practitioner for the purpose of inducing him to prescribe or supply medicinal products of that description,

(b) to a patient or client of a practitioner for the purpose of inducing him to request the practitioner to prescribe medicinal products of that description, or

(c) to a person for the purpose of inducing him to purchase medicinal products of that description from a person selling them by retail,

shall be guilty of an offence.

(4) Where in the circumstances specified in subsection (2) 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 subsections (3)(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, shall be guilty of an offence.

(5) Where a person is charged with an offence under this section, it shall be a defence for him to prove -

(a) where the offence charged is under subsection (1) or (3), that he did not know, and could not with reasonable diligence have discovered, that the advertisement or representation was false or misleading, or

(b) where the offence charged is under subsection (2) or (4), that he did not know, and could not with reasonable diligence have discovered, that the recommendations made by the advertisement or representation were unauthorised recommendations.

(6) Without prejudice to subsection (5), where a person is charged with an offence under this section in respect of the issue of an advertisement, it shall be a defence for him to prove that he is a person whose business it is to issue or arrange for the issue of advertisements, and that either -

(a) he received the advertisement for issue in the ordinary course of business and issued it, or arranged for it to be issued, either unaltered or without any alteration except in respect of lettering or lay-out, or

(b) not being a commercially interested party, he received from a commercially interested party the information on which the advertisement was based and in the ordinary course of business prepared the advertisement in accordance with that information for issue at the request of that party,

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

(7) For the purposes of this section an advertisement (whether it contains an accurate statement of the composition of medicinal products of the description in question or not) shall be taken to be false or misleading if (but only if) -

(a) it falsely describes the description of medicinal products to which it relates, or

(b) it is likely to mislead as to the nature or quality of medicinal products of that description or as to their uses or effects,

and any reference in this section to a false or misleading representation shall be similarly construed.

(8) The preceding provisions shall have effect subject to section 4(Contravention due to default of other person).

(9) Any person guilty of an offence under this section shall be liable -

(a) on summary conviction, to a fine not exceeding level 3 on the uniform scale,

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

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

Advertisements requiring consent of a holder of a recognised marketing authorisation.

74. (1) Where a recognised marketing authorisation is in force which is applicable to medicinal products of a particular description, then, except with the consent of the holder of that 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) Subject to section 124 (Contravention due to default of other person), any person who contravenes the preceding subsection shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 3 on the uniform scale.

Powers to regulate advertisements and representations.

75. (1) The Department may by regulations prohibit any one or more of the following, that is to say -

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

(b) the issue of advertisements likely to lead to the use of any medicinal product, or any other substance or article, for the purpose of treating or preventing a disease specified in the regulations or for the purpose of diagnosis of a disease so specified or of ascertaining the existence, degree or extent of a physiological condition so specified or of permanently or temporarily preventing or otherwise interfering with the normal operation of a physiological function so specified, or for the purpose of artificially inducing a condition of body or mind so specified,

(c) the issue of advertisements likely to lead to the use of medicinal products of a particular description or falling within a particular class specified in the regulations, or the use of any other substance or article of a description or class so specified, for any such purpose as is mentioned in paragraph (b), or

(d) the issue of advertisements relating to medicinal products and containing a word or phrase specified in the regulations, as being a word or phrase which, in the opinion of the 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) Where any regulations are made in accordance with subsection (1)(b), (c) or (d), the regulations may prohibit the making of any representation likely to lead to the use of a medicinal product or other substance or article to which the regulations apply for a purpose specified in the regulations in accordance with subsection (1)(b), or containing a word or phrase specified in the regulations in accordance with subsection (1)(d) if the representation -

(a) is made in connection with the sale or supply, or offer for sale or supply, of a medicinal product or other substance or article to which the regulations apply,

(b) is made to a person for the purpose of inducing him to purchase such a medicinal product, substance or article from a person selling by retail medicinal products or other substances or articles to which the regulations apply, or

(c) in the case of medicinal products of a description to which the regulations apply, is made to a practitioner for the purpose of inducing him to prescribe or supply medicinal products of that description or is made to a patient or client of a practitioner for the purpose of inducing him to request the practitioner to prescribe medicinal products of that description.

(3) Without prejudice to the preceding provisions, the Department may by regulations impose such requirements as, for any of the purposes specified in the next following subsection, they consider necessary or expedient with respect to any one or more of the following matters, that is to say -

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

(b) the form of any such advertisements,

(c) in the case of advertisements by way of cinematograph films or television, the duration for which, and the manner in which, any part of such an advertisement which contains particulars of a description specified in the regulations must be exhibited, and

(d) any provision of any enactment which the Department considers relevant,

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, and

(c) promoting safety in relation to such products.

(5) Without prejudice to the application of section 132 (Ordinances, orders and regulations), any prohibition imposed by regulations under this section may be a total prohibition or may be imposed subject to such exceptions as may be specified in the regulations.

(6) Any regulations made under this section may provide that any person who contravenes the regulations shall be guilty of an offence and -

(a) shall be liable on summary conviction to a fine not exceeding level 3 on the uniform scale or such lesser sum as may be specified in the regulations, and

(b) if the regulations so provide, shall be liable on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both.

(7) Section 72(3) (Scope of Part VI), shall not have effect for the purposes of subsections (1)(b) to (d).

Advertisements and representations directed to practitioners.

76. (1) On and after the relevant date, no advertisement relating to medicinal products of a particular description, other than a data sheet, shall be sent or delivered to a practitioner -

(a) by a commercially interested party, or

(b) by any person at the request or with the consent of a commercially interested party,

unless the conditions specified in subsection (3) are fulfilled.

(2) On and after the relevant date, no representation likely to promote the use of medicinal products of a particular description referred to in the representation shall be made to a practitioner by a person carrying on a relevant business, or by a person acting on behalf of a person carrying on such a business, unless the conditions specified in subsection (3) are fulfilled.

(3) Those conditions are -

(a) that a data sheet relating to medicinal products of the description in question is sent or delivered to the practitioner with the advertisement, or is delivered to him at the time when the representation is made, or that such a data sheet has been sent or delivered to him not more than fifteen months before the date on which the advertisement is sent or delivered or the representation is made, and

(b) that the advertisement or representation is not inconsistent with the particulars contained in the data sheet.

(4) For the purposes of this section, the relevant date -

(a) in relation to medicinal products of any description to which neither section 16(2) or (3) (Transitional exemptions) is applicable, is the first appointed day, and

(b) in relation to medicinal products of any description to which either of those subsections is applicable, is the date of expiry of the period of six months from the date (or, if more than one, the latest date) on which, by virtue of one or more orders under section 17 (Termination of transitional exemptions), those subsections cease (or, if only one of them is applicable, that subsection ceases) to have effect in relation to them.

(5) Subject to section 124 (Contravention due to default of other person), any person who contravenes subsection (1) or (2) shall be guilty of an offence, and, if he contravenes that subsection by not complying with the conditions specified in subsection (3)(b), shall be liable -

(a) on summary conviction, to a fine not exceeding level 3 on the uniform scale, or

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

and, in any other case, shall be liable on summary conviction to a fine not exceeding level 3 on the uniform scale.

(6) In this and the next section "**data sheet**" means a document relating to medicinal products of a particular description, which is prepared by or on

behalf of the holder of a marketing authorisation which is applicable to medicinal products of that description and which -

(a) complies with such requirements as to dimensions and form, as to the particulars to be contained in it, and as to the manner (whether in respect of type, size, colour or disposition or lettering or otherwise) in which any such particulars are to be so contained, as may be prescribed by regulation of the Department for the purposes of this subsection, and

(b) does not contain any information relating to medicinal products of that description except the particulars so prescribed.

(7) Nothing in this section applies in relation to a relevant medicinal product, as may be defined by any regulations made by the Department in respect of which there may be required to exist a summary of product characteristics.

Power for regulatory authority to require copies of advertisements.

77. (1) The regulatory authority may serve on any person a notice requiring him, within such time as may be specified in the notice, to furnish to the regulatory authority such number of copies (not exceeding twelve) as may be so specified of any advertisement (including any data sheet) relating to medicinal products, or to medicinal products of a description or falling within a class so specified, which he has issued, or has caused to be issued, within the period of twelve months ending with the date of service of the notice, and which he has so issued, or caused to be issued, -

(a) being a commercially interested party, or

(b) at the request or with the consent of a commercially interested party.

(2) Any person who without reasonable excuse fails to comply with any requirement imposed on him by a notice under this section shall be guilty of an offence, and shall be liable on summary conviction to a fine not exceeding level 3 on the uniform scale.

PART VII
VETERINARY MEDICINAL PRODUCTS AND VETERINARY SURGEONS

Definition of veterinary medicinal product.

78. For the purposes of this Part, a veterinary medicinal product that is -

(a) any substance, or combination of substances, presented as having properties for treating or preventing disease in animals, or

(b) any substance, or combination of substances, that may be used in, or administered to, animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis,

is hereafter referred to as a "**veterinary medicinal product**".

The regulatory authority.

79. For the purposes of this Part, the authority responsible for any recognition, grant, renewal, variation, suspension and revocation of licences, authorisations and certificates, shall be the appropriate Department.

Administration of veterinary medicinal products

Veterinary medicinal products on prescription only.

80. (1) The States may by Ordinance specify descriptions or classes of veterinary medicinal products for the purposes of this Law; and, in relation to any description or class so specified, the Ordinance shall state which of the -

(a) veterinary surgeons, and

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

are to be appropriate practitioners for the purposes.

(2) The descriptions of persons which may be specified in an Ordinance by virtue of subsection (1)(b) are a description of persons whose profession is regulated by or under a provision of any enactment and which the appropriate Department considers it appropriate to specify.

(3) Subject to the following provisions -

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

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

(4) Subsection (3)(a) shall 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 who is an appropriate practitioner.

(5) Any Ordinance made by the Department for the purposes of this section may provide -

(a) that subsection (3)(a) or (b), or both those subsections, shall have effect -

(i) subject to such exemptions as may be specified in the Ordinance, or

(ii) where the appropriate practitioner is an appropriate practitioner by virtue of provision made under subsection (1)(b), such modifications as may be so specified, and

(b) that, for the purpose of subsection 3(a), a veterinary medicinal product shall not be taken to be sold or supplied in accordance with a prescription given by an appropriate practitioner unless such conditions as are prescribed by the Ordinance are fulfilled.

(6) An Ordinance under this section may provide, in relation to a person who is an appropriate practitioner by virtue of subsection (1)(b), that such a person may -

(a) give a prescription for a veterinary medicinal product falling within a description or class specified in the Ordinance,

(b) administer any such product, or

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

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

(7) An Ordinance under this section may provide, in relation to any condition specified by virtue of subsection (6), for the condition to have effect subject to such exemptions as may be specified in the Ordinance.

(8) Where a condition is specified by virtue of subsection (6), any prescription or direction given by a person in contravention of the condition is not (subject to such exemptions or modifications as may be specified in the Ordinance by virtue of subsection (5)(a)) given by an appropriate practitioner for the purposes of subsection (3)(a) or (b) .

(9) Any exemption conferred, or modification made by an Ordinance in accordance with subsection (5)(a) or (7) may be conferred, or made subject to such conditions or limitations as may be specified in the Ordinance.

Requirement to specify certain products for veterinary use as prescription-only, non-food animal or authorised veterinary medicinal products.

81. (1) There shall be the following categories of authorised veterinary medicinal products -

(a) Prescription Only Medicine - Veterinarian (abbreviated to POM-V),

(b) Prescription Only Medicine - Veterinarian, Pharmacist, Suitably qualified Person (abbreviated to POM - VPS),

(c) Non-Food Animal - Veterinarian, Pharmacist, Suitably Qualified Person (abbreviated to NFA-VPS), and

(d) Authorised Veterinary Medicine - General Sales List (abbreviated to AVM - GSL).

(2) The classifications of the above products shall be -

(a) those given by the Secretary of State in exercise of his powers under Part 1 of Schedule 3 to the Veterinary Medicines Regulations 2007[r], or

(b) as otherwise prescribed by regulations of the appropriate Department.

(3) The appropriate Department shall exercise its powers under this section, as to secure that every product -

(a) in respect of which a marketing authorisation is recognised, and

(b) to which subsection (4) or (5) applies,

falls within one of the descriptions or classes of authorised veterinary medicinal products.

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[r] UK SI 2007 No. 2539 (which revoked and remade SI 2006 No. 2407).

(4) This subsection applies to any product which -

(a) is subject to restrictions on supply or use resulting from the Narcotic Drugs Convention, the Psychotropic Substances Convention or any provision of any other enactment,

(b) is likely to cause unnecessary risk to the target species, humans or the environment unless special precautions are taken by a veterinary surgeon,

(c) is intended for a treatment or condition which requires a precise prior diagnosis, or

(d) may cause effects which impede or interfere with subsequent diagnosis or treatment.

(5) This subsection applies to any new product containing an active ingredient where a marketing authorisation for veterinary use was granted in respect of the ingredient less than five years prior to the relevant date in relation to the product unless, having regard to -

(a) the information and particulars provided by the applicant for the licence, or

(b) experience acquired in the use of the product,

the appropriate Department is satisfied, having taken advice from the Committee, that subsection (4) does not apply to the product.

(6) For the purposes of subsection (5) the relevant date in relation to a product is the date on which it falls to be determined by the appropriate Department whether subsection (5) applies to the product.

(7) Section 36(5) applies for the purposes of this section.

Administration of a veterinary medicinal product outside the terms of a marketing authorisation.

82. (1) Notwithstanding the provisions of Part II, a veterinary surgeon may either administer a veterinary medicinal product prescribed by him personally or may direct another person to do so under his responsibility.

(2) If there is no authorised veterinary medicinal product available in the Bailiwick for a particular condition, the veterinary surgeon responsible for the animal may, in particular to avoid unacceptable suffering, treat the animal concerned with the following ("**the cascade**") cascaded in the following order –

(a) a veterinary medicinal product authorised in the Bailiwick or the United Kingdom for use with another animal species, or for another condition in the same species,

(b) if and only if there is no such product that is suitable, either –

(i) a medicinal product authorised in the Bailiwick or the United Kingdom, or

(ii) a veterinary medicinal product not authorised in the Bailiwick or the United Kingdom, but authorised in another member State and

approved by the appropriate Department for use with any animal species (in the case of a food-producing animal, it must be a food producing species and the Department may give further directions as to the particular substances that may be administered), or

(c) if and only if there is no such product that is suitable, a veterinary medicinal product prepared extemporaneously by a pharmacist, a veterinary surgeon, or a person holding a manufacturing authorisation authorising the manufacture of that type of product.

(3) The appropriate Department may, by order, make further provisions relating to the administration of a veterinary product outside the terms of a recognised marketing authorisation which may include, without limitation, provisions relating to withdrawal periods, administration to food-producing horses, immunological products, treatment in exceptional circumstances and administration by veterinary surgeons practising outside the Bailiwick.

(4) Without prejudice to the provisions of Part II, the appropriate Department may, if it considers it appropriate, make further provision relating to, without limitation, the placing on the market, importation and administration of a veterinary medicinal product without a recognised marketing authorisation, for certain animals, or classes or description of animals.

Supply and classification of veterinary medicinal products and sheep dip.

83. Notwithstanding the provisions of Part II, the appropriate Department may, by regulations, prescribe further conditions relating to the supply (whether by veterinary surgeon, pharmacist or any other suitably qualified person) and classification of veterinary medicinal products and sheep dip.

Prohibition of sale, supply or importation of veterinary medicinal products of specified description, or of animal feeding stuffs incorporating such products.

84. (1) Subject to the following provisions, the appropriate Department, where it appears to it to be necessary to do so in the interests of safety, may by order prohibit the sale, supply or importation, of veterinary medicinal products of any description, or falling within any class, designate particular animal feeding stuffs incorporating such veterinary medicinal products and prohibit the sale or supply, or the importation, of those particular products.

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

(3) Before making an order under this section the appropriate Department, shall consult the appropriate committee, unless in its opinion it is essential to make the order with immediate effect to avoid serious danger to health, whether of human beings or of animals.

(4) Where an order is made under this section without any consultation in accordance with subsection (3), the prohibition imposed by the order shall not exceed three months from the date on which it comes into operation, as may be specified in the order. This provision is without prejudice to the making of any further order in accordance with the provisions (including this subsection).

Medicinal tests on animals

Medicinal tests on animals.

85. (1) Subject to the following provisions, no person shall, in the course of a business carried on by him -

(a) sell or supply any veterinary medicinal product for the purposes of a medicinal test on animals,

(b) procure the sale or supply of any veterinary medicinal product for the purposes of such a test, or

(c) procure the manufacture or assembly of any veterinary medicinal product for sale or supply for the purposes of such a test,

unless one or other of the conditions specified in subsection (2) is fulfilled.

(2) Those conditions are -

(a) that he is the holder of a recognised marketing authorisation which authorises the test in question, or he does it to the order of the holder of such a recognition, and (in either case) he does it in accordance with that recognition, and

(b) that a certificate for the purposes (in this Law referred to as an "**animal test certificate**") has been issued certifying that, subject to the provisions of the certificate, the regulatory authority have consented to the test in question and that certificate is for the time being in force and the test is to be carried out in accordance with that certificate.

(3) Subject to the following provisions, no person shall import any veterinary medicinal product for the purposes of a medicinal test on animals unless either -

(a) he is the holder of a recognised marketing authorisation which authorises that test, or imports the product to the order of the holder of such an authorisation, and (in either case) he imports it in accordance with that authorisation, or

(b) an animal test certificate has been issued certifying as mentioned in subsection (2)(b) and that certificate is for the time being in force and the test is to be carried out in accordance with that certificate.

(4) Subject to the following provisions, no person shall, in the course of a business carried on by him, administer any substance or article to an animal by way of a medicinal test on animals, or procure any substance or article to be so administered, unless either -

(a) in the case of a veterinary medicinal product, there is in force a recognised marketing authorisation (whether held by him or by another person) which authorises that test and the product is administered in accordance with that authorisation or in accordance with any instructions required by the authorisation to be communicated to the person carrying out the test, or

(b) whether the substance or article is a veterinary medicinal product or not, an animal test certificate has been issued certifying as mentioned in subsection (2)(b) and that certificate is for the time being in force and the substance or article is administered in accordance with that certificate.

(5) A recognised marketing authorisation shall be taken to authorise a particular medicinal test on animals if -

(a) the substance or article to be administered in the test is a veterinary medicinal product of a description to which the authorisation relates, and

(b) the uses of veterinary medicinal products of that description which are referred to in the authorisation are such as to include their use for the purposes of that test.

(6) In this Law "**medicinal test on animals**" means an investigation or series of investigations consisting of any of the following, that is to say -

(a) the administration of a veterinary medicinal product of a particular description to one or more animals, where there is evidence that veterinary medicinal products of that description have effects which may be beneficial to, or otherwise advantageous in relation to, that animal or those animals, and the product is administered for the purpose of ascertaining whether, or to what extent, it has those or any other effects, whether advantageous or otherwise,

(b) the administration of a veterinary medicinal product to one or more animals in circumstances where there is no such evidence as is mentioned in paragraph (a), and the product is administered for the purpose of ascertaining whether, or to what extent, it has any effects relevant to a medicinal purpose,

(c) the administration of any substance or article, other than a veterinary medicinal product, to one or more animals for the purpose of ascertaining whether it has any effects relevant to a medicinal purpose.

Exemptions in respect of medicinal tests on animals.

86. (1) Subject to subsection (3), the restrictions imposed by sections 85(1) and (4) (Medicinal tests on animals) do not apply to a veterinary surgeon in respect of his -

(a) selling or supplying, or procuring the sale or supply of, a veterinary medicinal product for the purpose of its being administered to one or more animals which are under his care,

(b) procuring the manufacture or assembly of a veterinary medicinal product where the product is specially prepared to his order for the purpose of its being administered to one or more such animals, or

(c) administering a substance or article to an animal which is under his care, or procuring a substance or article to be so administered.

(2) Subsection (1) shall not have effect in relation to a veterinary surgeon where the medicinal test in question is to be carried out under arrangements made by, or at the request of, another person, and (where the arrangements are made by the veterinary surgeon and not at the request of any other person) shall not have effect so as to exempt from the restrictions in question anything done -

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

(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.

(3) Subject to subsection (5), the restrictions imposed by section 85(1) do not apply to anything which is done in a registered pharmacy and is done there by or under the supervision of a pharmacist and consists of dispensing a veterinary medicinal product in accordance with a prescription given by a veterinary surgeon; 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 veterinary medicinal product in accordance with a prescription given by a veterinary surgeon or of procuring the assembly of a veterinary medicinal product.

(4) Subject to subsection (5), the restrictions imposed by section 85(1) also do not apply to anything done in relation to a veterinary medicinal product where -

(a) it is done by the person who, in the course of a business carried on by him, has manufactured or assembled the product to the order of a veterinary surgeon who has stated that it is required for administration to an animal or herd which is under his care, or is required, at the request of another veterinary surgeon , for administration to an animal or

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

(b) it is done by the person who, in the course of a business carried on by him, has manufactured or assembled the product to the order of a pharmacist in accordance with a prescription given by a practitioner, or

(c) it consists of selling the product by way of wholesale dealing where it has been manufactured or assembled in the circumstances specified in paragraph (a) or (b).

(5) The exemptions conferred by subsections (3) and (4) do not apply to a vaccine specially prepared for administration to poultry, and do 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 has been specially prepared for administration to one or more animals in the herd from which it is derived.

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

87. (1) Subject to the following provisions, no person shall in the course of a business carried on by him sell or supply for human consumption an animal to which 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.

Supplementary provisions as to medicinal tests on animals.

88. (1) The restrictions imposed by section 7 (General provisions as to dealing with medicinal products), do not apply to anything done in accordance with an animal test certificate.

(2) The restrictions imposed by section 8(2) (Provisions as to manufacture and wholesale dealing), do not apply to the manufacture or assembly of any veterinary medicinal product for the sole purpose of its being administered by way of a medicinal test on animals, or of its being sold, supplied or exported for the sole purpose of its being so administered, unless the product falls within a class of veterinary medicinal products specified in an order made for the purposes of this paragraph by the appropriate Department.

(3) No class of veterinary medicinal products shall be specified in an order for the purposes of subsection (2) unless it appears to the appropriate

Department to be requisite to do so for securing that the exemption conferred by that paragraph does not apply to veterinary medicinal products consisting wholly or partly of substances the purity or potency of which cannot, in their opinion, be adequately tested by chemical means.

(4) Neither the restrictions imposed by section 7 (General provisions as to dealing with medicinal products), nor those imposed by section 85(1) (Medicinal tests on animals), apply to anything done in relation to a veterinary medicinal product for the purposes of a medicinal test on animals which is to be carried out wholly outside the Bailiwick, unless the product falls within a class specified in an order made for the purposes of subsection (2).

(5) Where the holder of a manufacturer's licence, or recognised manufacturer's licence, manufactures or assembles any veterinary medicinal product for sale or supply for the purposes of a medicinal test on animals, and -

(a) an animal test certificate has been issued and is for the time being in force in respect of that test, and the test is to be carried out in accordance with that certificate, and

(b) the product is so manufactured or assembled as to comply with any requirements of the certificate relating to the products to be administered in the test,

then if the conditions specified in paragraph 7(1) of Schedule 2 (Special provisions as to effect of manufacturer's licence) are not fulfilled in relation to the product, that paragraph shall have effect in relation to it as if those conditions were fulfilled.

(6) Without prejudice to subsection (5), paragraph 7 of Schedule 2 (Special provisions as to effect of manufacturer's licence), shall not have effect in relation to the manufacture or assembly of any veterinary medicinal product for sale

or supply for the purposes of a medicinal test on animals, where the product falls within a class specified in an order made for the purposes of subsection (2).

(7) For the purposes of section 85 (Medicinal tests on animals), a person shall not be treated as doing anything, or procuring anything to be done, for the purposes of a medicinal test on animals if -

(a) the test is, or is to be, carried out under arrangements to which he is not a party, and

(b) he has not been informed of those arrangements.

(8) The appropriate Department may by order provide that section 85, shall have effect subject to such exemptions (other than those for the time being having effect by virtue of section 86 (Exemptions in respect of medicinal tests on animals), and subsection (4)) as may be prescribed.

(9) Any exemption conferred by an order under subsection (8) may be conferred subject to such conditions or limitations as may be specified in the order.

(10) The appropriate Department may, by order, provide that any of the provisions of section 86 or subsection (4), shall cease to have effect, or shall have effect subject to such exceptions or modifications as may be specified in the order.

Application for, and issue of, animal test certificate.

89. (1) Any application for an animal test certificate shall be made to the regulatory 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 by order of the appropriate Department.

(2) In dealing with any such application, the regulatory authority shall have regard in particular to any evidence available to them as to any risks involved in the proposed medicinal test on animals.

(3) Subject to section 90 (Duration and renewal of animal test certificate), the provisions of paragraphs 3 to 6 of Schedule 2, shall have effect in relation to applications for animal test certificates, as if in those paragraphs any reference to a licence under this Part, were a reference to such a certificate.

Duration and renewal of animal test certificate.

90. (1) Subject to the following provisions, every animal test certificate, unless previously renewed or revoked, shall expire at the end of the period of two years from the date on which it was issued 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 certificate as issued or last renewed.

(2) Any such certificate, if it has not been revoked, may, on the application of the holder of the certificate, be renewed by the regulatory authority for a further period of two years from the date on which it would otherwise expire or such shorter period from that date as the regulatory authority may determine.

(3) Sections 89(1) and (2) (Application for and issue of, animal test certificate) shall have effect in relation to applications for the renewal of such certificates as they have effect in relation to applications for the issue of such certificates.

(4) On an application for the renewal of such a certificate the regulatory authority –

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

(b) may issue to the applicant a new animal test certificate containing such provisions as the regulatory authority consider appropriate, or

(c) if, having regard to the provisions, they consider it necessary or expedient to do so, may refuse to renew the certificate or to issue a new certificate.

(5) In relation to any such application the provisions of paragraphs 3(1)(c), (5) and (6) and 4 to 6 of Schedule 2 shall have effect as if in those provisions any reference to refusing a licence, included a reference to refusing to renew an animal test certificate and any reference to granting such a licence included a reference to renewing such a certificate.

(6) Every application for the grant or renewal of an animal test certificate shall, unless it otherwise expressly provides, be taken to be an application for the grant or renewal of the certificate for the full period of two years mentioned in subsection (1) or (2), as the case may be; and in any provisions of paragraphs 4 to 6 of Schedule 2, as applied by subsection (5) any reference to the grant or renewal of a certificate otherwise than in accordance with the application shall be construed accordingly.

(7) Where an application for the renewal of such a certificate has been duly made -

(a) the certificate shall not cease to be in force by virtue of the preceding provisions before the regulatory authority have determined the application, and

(b) if by an interim order made under section 112(3)(a) (Validity of decisions and proceedings relating

thereto), the operation of the decision of the regulatory authority on the application is suspended, the certificate 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 or variation of animal test certificate.

91. (1) Subject to the following provisions, the regulatory authority may suspend, for such period as the authority may determine, an animal test certificate, or may revoke, or vary the provisions of, any such certificate.

(2) The powers conferred by this section shall only be exercisable by the regulatory authority on one or more of the following grounds -

(a) that the matters stated in the application on which the certificate was issued were false or incomplete in a material particular,

(b) that any of the provisions of the certificate has to a material extent been contravened,

(c) that veterinary medicinal products of any description to which the certificate relates, as sold, supplied, exported, imported, manufactured or assembled for the purposes of the medicinal test on animals to which it relates, fail to a material extent to correspond to the characteristics by reference to which the certificate was issued,

(d) that the holder of the certificate has without reasonable excuse failed to comply with a requirement imposed on him under section 20(2) (Provision of information to

regulatory authority) to furnish information to the regulatory authority with respect to any substances or articles to which the certificate relates,

(e) that any such substances or articles can no longer be regarded as substances or articles which can safely be administered for the purposes of the medicinal test on animals to which the certificate relates, or

(f) that the specification and standards to which any such substances or articles are manufactured can no longer be regarded as satisfactory.

(3) The provisions of Schedule 3 to this Law shall have effect in relation to an animal test certificate as they have effect in relation to a recognised marketing authorisation, as if in paragraph 1 of that Schedule the reference to paragraph (g) or paragraph (h) of paragraph 9(3), were a reference to paragraph (e) or paragraph (f) of subsection (2).

(4) Without prejudice to any power exercisable by virtue of the preceding provisions, the regulatory authority may, on the application of the holder of an animal test certificate, vary the provisions of the certificate in accordance with any proposals contained in the application if they are satisfied that the variation will not adversely affect the safety, quality or efficacy of veterinary medicinal products of any description to which the certificate relates.

Animal feeding stuffs

Special enforcement and sampling provisions relating to animal feeding stuffs.

92. (1) For the purposes of the application of the provisions of sections 116 (Power to inspect, take samples and seize goods and documents), 117 (Application of sampling procedure to substance or article seized under section 116)

and 119 (Analysis of samples in other cases) in relation to animal feeding stuffs, regulations made by the appropriate Department may provide that any of those provisions specified in the regulations shall have effect subject to such modifications as may be so specified.

(2) Regulations made by the appropriate Department -

(a) may make provision as to the manner in which samples may be taken by virtue of the provisions of section 116 as modified by any regulations made under the subsection (1), as to the manner in which samples may be set aside, or substances or articles may be treated as samples, by virtue of the provisions of section 117 as so modified, or as to the manner in which samples may be submitted for analysis by virtue of the provisions of section 119 as so modified, and

(b) in relation to samples so taken, set aside or submitted for analysis, or substances or articles so treated as samples, may make provision (either in substitution for, or by way of modification of or addition to, any of the provisions of Schedule 4) as to the manner in which such samples, substances and articles are to be dealt with.

(3) For the purposes of proceedings for such offences under this Law relating to animal feeding stuffs as may be prescribed by regulations made under subsection (2), the regulations may -

(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.

(4) In relation to the incorporation in animal feeding stuffs of substances or articles of any description or class specified in an order made under this subsection by the appropriate Department, so much of any licence granted or recognised licence or marketing authorisation, or animal test certificate issued under Part II, as imposes any restriction or requirement by reference to the quantity to be incorporated, or the proportion in which any substance or article may be incorporated, in any animal feeding stuff shall not be taken to be contravened in any particular case if the discrepancy does not exceed such limit as may be specified by the order in relation to substances or articles of that description or class.

(5) Where a label or mark on a container or package containing any animal feeding stuff, or a leaflet supplied or to be supplied with any animal feeding stuff, specifies a quantity or proportion of a medicinal product of a particular description as being incorporated in the animal feeding stuff, section 94(2) (Provisions as to medicated feeding stuffs) shall not be taken to be contravened by reason only that the quantity or proportion actually incorporated in the animal feeding stuff is greater or less than that so specified, if the discrepancy does not exceed such limit as the appropriate Department may by order specify in relation to medicinal products of that description, or in relation to a class of medicinal products which includes medicinal products of that description.

(6) The powers conferred by subsection (2) shall be exercisable in addition to any power exercisable by virtue of paragraph 27 of Schedule 4 (Power to modify sampling provisions).

(7) References in subsections (1) and (3) to (5) to animal feeding stuffs include a reference to any medicated feeding stuff, within the meaning of section 133(4).

Medicated animal feeding stuffs.

93. (1) The appropriate Department may by regulations prohibit 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 unless such of the conditions mentioned in subsection (2), as may be specified in the regulations, are satisfied.

(2) The conditions referred to are -

(a) that it is incorporated in accordance with provisions relating to the incorporation of the veterinary medicinal product in animal feeding stuffs contained in a recognised marketing authorisation or animal test certificate (whether held by him or by another person),

(b) that it is incorporated in accordance with a written direction given by a veterinary surgeon, being a written direction complying with such requirements as may be specified in the regulations, or

(c) that the person concerned is for the time being entered in a register kept for the purposes of the regulations by the veterinary medicines registrar.

(3) A condition imposed by virtue of subsection (2)(a) shall be taken to be satisfied if the person incorporating the veterinary medicinal product in the animal feeding stuff -

(a) is not the holder of a recognised marketing authorisation or animal test certificate containing such provisions as are mentioned in that subsection, but

(b) believes, on reasonable grounds, that another person is the holder of such an authorisation or certificate containing such provisions and that the veterinary medicinal product is incorporated in accordance with those provisions.

(4) The appropriate Department may by regulations prohibit -

(a) the sale, offer for sale, supply or export 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, or

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

unless such of the conditions mentioned in subsection (5) as may be specified in the regulations are satisfied.

(5) The conditions referred to are -

(a) that the veterinary medicinal product was not incorporated in the animal feeding stuff in

contravention of any prohibition imposed under subsection (1),

(b) that the feeding stuff is sold, offered for sale, supplied, exported or imported (as the case may be) in accordance with a written direction given by a veterinary surgeon, being a written direction complying with such requirements as may be specified in the regulations, or

(c) that the person concerned is for the time being entered in a register kept for the purposes of the regulations by the veterinary medicines registrar.

(6) A condition imposed under subsection (5)(a) shall be taken to be satisfied if the person selling, offering for sale, supplying, exporting or importing the animal feeding stuff -

(a) did not incorporate the veterinary medicinal product in it, and

(b) had no reasonable grounds to believe that it was incorporated in contravention of any prohibition imposed by virtue of subsection (1).

(7) Regulations under this section may impose such conditions as the appropriate Department thinks fit in respect of the inclusion or retention of persons in a register kept for the purposes of the regulations, including conditions requiring the payment to the veterinary medicines registrar of fees of such amounts as the appropriate Department may determine.

(8) In determining any such fees, the appropriate Department may have regard to any costs incurred or to be incurred by any other person for the purpose of maintaining or improving standards among those engaged in the activities referred to in subsections (1) and (4).

(9) Any fees received for the inclusion or retention of any person in a register kept for the purposes of the regulations shall, if the appropriate Department so determine, be applied to such extent and in such manner as they may determine towards meeting any costs falling within subsection (8).

(10) A person contravenes this section if he contravenes any prohibition imposed under subsection (1) or (4).

(11) References in this Law to the incorporation of a veterinary medicinal product in an animal feeding stuff do not include a reference to it being so incorporated in the course of making a veterinary medicinal product; but, subject to that, they include a reference to the incorporation -

(a) for a medicinal purpose of a substance or article other than a veterinary medicinal product, or

(b) of a substance in which a veterinary medicinal product has been incorporated,

in an animal feeding stuff.

(12) In this Part, "**the veterinary medicines registrar**" means any person appointed by the appropriate Department as registrar for the purpose of this Part.

Provisions as to medicated animal feeding stuffs.

94. (1) Subject to subsection (2) and section 104 (Application of Part V of this Law to veterinary medicinal products), 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 of supply, any animal feeding stuff in which a veterinary medicinal product of any description has been incorporated, which is in a container or package labelled or marked in such a way that the container or package -

(a) falsely describes the animal feeding stuff in so far as its composition results from the incorporation of the veterinary medicinal product in it, or

(b) is likely to mislead as to the nature or quality of the animal feeding stuff in so far as its composition so results, or

(c) is likely to mislead as to the uses or effects of animal feeding stuffs in which veterinary medicinal products of the description in question have been incorporated, in so far as any such uses or effects are attributable to the incorporation of such veterinary medicinal products;

and no person shall, in the course of a business carried on by him, supply with any such animal feeding stuff, or have in his possession for the purpose of so supplying, a leaflet which falsely describes the animal feeding stuff, or is likely to mislead, as mentioned in paragraph (a), (b) or (c).

(2) For the purposes of subsection (1) no account shall be taken -

(a) of any mark which is made on a container or package in pursuance of any regulations made by the appropriate Department which relate to material being

sold in the course of trade which is used as a fertilizer or feeding stuff, or

(b) of any statement which, in pursuance of that Part, is made in any leaflet supplied, or intended to be supplied, with any material.

(3) In this section -

"**animal**" means any living creature except man,

"**feeding stuff**" means -

(a) a product of vegetable or animal origin in its natural state (whether fresh or preserved),

(b) a product derived from the industrial processing of such a product, or

(c) an organic or inorganic substance, used singly or in a mixture,

whether or not containing additives, for oral feeding to animals, and

"**fertiliser**" means a fertiliser used for the cultivation of crops or plants of any description, including trees.

Further provisions as to medicated feeding stuffs and specified feed additives.

95. The appropriate Department may, by order, make further provision for the regulation of medicated animal feeding stuffs and for any animal feed additives specified in the order, as it thinks fit.

Application of Parts of this Law to veterinary medicinal products

Application of Part 1 of this Law to veterinary medicinal products.

96. The provisions of Part 1 of this Law apply to any veterinary medicinal product as they apply to all medicinal products under this Law, or any provision made under it, subject to such exceptions, adaptations and modifications as the context requires or as the appropriate Department may, by order, prescribe.

Application of Part II of this Law to veterinary medicinal products.

97. (1) The provisions of Part II apply to any veterinary medicinal product as they apply to all medicinal products under this Law, or any provision made under it, subject to -

(a) subsections (5) and (6), and

(b) such exceptions, adaptations and modifications as the context requires, or as the appropriate Department may, by order, prescribe,

and save for the exemptions described in subsection (2).

(2) Subject to subsections (3) and (4), the exemptions for the purpose of subsection (1) are as follows -

(a) where the product is –

(i) a vaccine, toxin or serum,

(ii) a product based on radioactive isotopes,

(iii) a product specially prepared for administration by a veterinary surgeon

to a particular animal or herd which is under his care, or

(iv) an animal feeding stuff prescribed by regulations made by the appropriate Department,

the restrictions imposed by sections 7(2) and 7(3) (General provisions as to dealing with medicinal products) do not apply,

(b) where the product which a person distributes is a veterinary medicinal product, section 8(7)(b) (Provisions as to manufacture and wholesale dealing) does not apply if the product is -

(i) a vaccine, toxin or serum,

(ii) a product based on radioactive isotopes,

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

(iv) a homoeopathic veterinary medicinal product, or

(v) an additive for animal feeding stuffs in relation to which the appropriate Department has made regulations under paragraph (a)(iv),

(c) the restrictions imposed by sections 7 (General provisions as to dealing with medicinal products) and 8 (Provisions as to manufacture and wholesale dealing) do not apply to anything done by a veterinary surgeon which -

(i) relates to a veterinary 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

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

(d) the restrictions imposed by sections 7 (General provisions as to dealing with medicinal products) and 8 (Provisions as to manufacture and wholesale dealing)

do not apply to the preparation or dispensing in a registered pharmacy of a veterinary 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 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.

(3) The appropriate Department may, by regulations, prescribe that the preceding provisions do not exempt from the restrictions imposed by sections 7 (General provisions as to dealing with medicinal products) and 8 (Provisions as to manufacture and wholesale dealing), anything done in a registered pharmacy by or under the supervision of a pharmacist in relation to any particular, or any class or description of veterinary medicinal product.

(4) Subsection (2)(c) does not exempt from the restrictions imposed by sections 7 (General provisions as to dealing with medicinal products) and 8 (Provisions as to manufacture and wholesale dealing), anything done by a veterinary surgeon -

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

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

(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, or

(d) in relation to any, or any class or description of, veterinary medicinal product, that the appropriate Department may specify, by regulations.

(5) The exemption conferred by section 10(1) (Exemptions for pharmacists) 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.

(6) The provisions of section 20 (Provision of information to regulatory authority) apply to animal test certificates as they do to licences, whether granted or recognised.

Offences under Part II and certain provisions of this Part in relation to veterinary medicinal products.

98. (1) Subject to section 22 (Special defences under section 21), any person who contravenes any of the provisions of sections 7 (General provisions as to dealing with medicinal products), 8 (Provisions as to manufacture and wholesale dealing), 85 (Medicinal tests on animals), 87 (Restrictions as to animals on which

medicinal tests have been carried out) or 93 (Medicated animal feeding stuffs), 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 medicinal product or animal feeding stuff is imported in contravention of section 7 (General provisions as to dealing with medicinal products), 85 (Medicinal tests on animals), or 93 (Medicated animal feeding stuffs), any person who, otherwise than for the purpose of performing or exercising a duty or power imposed or conferred by or under this Law 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 recognised marketing authorisation or of an 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 recognition or certificate relates, and -

(a) does not communicate to that person the provisions of the recognition 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 regulatory 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 recognised marketing authorisation or of an animal test certificate, sells or supplies a substance or article,

to which the authorisation 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 authorisation or certificate which relate to the incorporation of that substance or article in animal feeding stuffs, or any instructions required by the authorisation 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 recognised marketing authorisation or animal test certificate as are mentioned in subsection (4) are varied by the regulatory authority, and on varying those provisions the regulatory authority serve on the holder of the authorisation 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 20 (Provision of information to regulatory authority), 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 20(2), shall be guilty of an offence.

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

(a) on summary conviction, to a fine not exceeding level 3 on the uniform scale,

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

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

Special defences under section 98.

99. (1) Where the holder of a recognised marketing authorisation or of an animal test certificate is charged with an offence under section 98 (Offences under Part II in relation to veterinary medicinal products) 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 or recognised manufacturer's licence is charged with an offence under section 98 in respect of any medicinal products which have been manufactured or assembled by him, in circumstances where he is not the holder of a marketing authorisation or of an 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 marketing authorisation applicable to those products, or of an animal test certificate applicable to them, and

(b) that the products were manufactured or assembled in accordance with that marketing authorisation or certificate.

Application of Part III of this Law to veterinary medicinal products.

100. (1) The provisions of Part III (Further provisions relating to dealings with medicinal products) apply to any veterinary medicinal product as they apply to all medicinal products under this Law, or any provision made under it, subject to such exceptions, adaptations and modifications as the context requires or as the appropriate Department may, by order, prescribe.

(2) Without prejudice to subsection (1) -

(a) the restrictions imposed by sections 29 (Sale or supply of medicinal products not on general sale list) and 30 (Sale or supply of medicinal products on general sale list) do not apply to the sale, offer for sale, or supply of a veterinary medicinal product by a veterinary surgeon for administration by him or under his direction to an animal or herd which is under his care,

(b) section 30(2) does not apply where the product is a veterinary medicinal product, and

(c) without prejudice to section 34(2) (Power to extend or modify exemptions) any order made under section 34(1) providing for the exemption from section 29 of the sale, or offer or exposure for sale, by retail or the

supply in circumstances corresponding to retail sale of veterinary medicinal products by any persons may –

(i) as a condition of the exemption, require those persons to be entered for the time being in a register of merchants in veterinary medicinal products kept by the veterinary medicines registrar, and

(ii) impose such conditions as the appropriate Department thinks fit in respect of the inclusion or retention of persons in the register, including conditions requiring the payment to the veterinary medicines registrar of fees of such amounts as the appropriate Department may determine.

(3) In determining the amount of any fees imposed under subsection (2)(c)(ii), the appropriate Department may have regard to any costs incurred or to be incurred by any person for the purpose of maintaining or improving standards among those engaged in the sale by retail of veterinary medicinal products or the supply of such products in circumstances corresponding to retail sale.

(4) Any fees received by virtue of conditions imposed under subsection (2)(c)(ii) shall, if the appropriate Department so determines, be applied to such extent, and in such manner, as the appropriate Department may determine.

Offences under Part III and certain provisions of this Part in relation to veterinary medicinal products.

101. (1) The following provisions have effect subject to sections 124 (Contravention due to default of other person) and 125 (Warranty as defence).

(2) Any person who gives a prescription or directions or administers a veterinary medicinal product in contravention of a condition imposed by an Ordinance under section 80(7) (Veterinary medicinal products on prescription only) shall be guilty of an offence.

(3) Any person who -

(a) is an appropriate practitioner by virtue of provision made under section 80(1), and

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

shall be guilty of an offence.

(4) Any person who contravenes any of the following provisions of Part III or this Part, that is to say, sections 29 (Sale or supply of medicinal products not on general sale list), 35 (Medicinal products on prescription only), 40 (Adulteration of medicinal products), 41 (Protection of purchasers of medicinal products) and 42 (Compliance with standards specified in monographs in certain publications), or who contravenes any regulations made under section 38 (Restricted sale, supply and administration of certain medicinal products) or 39 (Special restrictions on persons to be supplied with medicinal products) or any order made under section 84 (Prohibition of sale or supply, or importation, of veterinary medicinal products of specified description, or of animal feeding stuffs incorporating such products), shall be guilty of an offence.

(5) Where a veterinary medicinal product is sold, supplied or imported in contravention of an order made under section 84, any person who,

otherwise than for the purpose of performing or exercising a duty or power imposed or conferred by or under this Law or any other enactment, is in possession of the product, knowing or having reasonable cause to suspect that it was sold, supplied or imported in contravention of the order, shall be guilty of an offence.

(6) A person who has in his possession a veterinary medicinal product to which section 80(3)(a) applies, with the intention of supplying it otherwise than in accordance with the requirements of that section, shall be guilty of an offence.

(7) Any person guilty of an offence under subsection (2), (3), (4), (5) or (6) shall be liable -

(a) on summary conviction, to a fine not exceeding level 3 on the uniform scale,

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

(8) Any person who contravenes section 30 (Sale or supply of medicinal products on general sale list) or 31(1) (Sale of medicinal products from automatic machines) or an order made under section 31(2), shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 3 on the uniform scale.

(9) Any regulations made under section 43 (Further powers to regulate dealings with medicinal products), may provide that any person who contravenes the regulations shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the uniform scale or such lesser sum as may be specified in the regulations.

Disqualification on conviction of certain offences under section 101.

102. (1) Where in any proceedings a person is convicted of an offence under section 101(6) (Offences under Part III), in respect of any premises used for carrying on a retail pharmacy business, then, upon an application being made by Her Majesty's Procureur, the court by or before which he was convicted may (subject to the following provisions) make an order disqualifying him from using those premises for the purposes of such a business for such period, not exceeding two years, as may be specified in the order.

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

(a) to the gravity of the offence of which he has been convicted as mentioned in subsection (1), or

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

(c) to any offences under section 101(6), of which he has previously been convicted.

(3) No order under this section shall be made against a person on the application of Her Majesty's Procureur unless that person has, not less than fourteen days before the date of the hearing, been given notice in writing of the intention to apply for such an order.

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

(5) Subject to subsection (6), at any time after the end of the period of six months from the date on which an order under this section comes into force, the person to whom the order relates may apply to the court by which the order was made to revoke the order or to vary it by reducing the period of disqualification.

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

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

Application of Part IV of this Law to veterinary medicinal products.

103. (1) The provisions of Part IV (Pharmacies) apply to any veterinary medicinal product as they apply to all medicinal products under this Law, or any provision made under it, subject to such exceptions, adaptations and modifications as the context requires or as the appropriate Department may, by order, prescribe.

Application of Part V of this Law to veterinary medicinal products.

104. (1) The provisions of Part V (Containers, packages and identification of medicinal products) apply to any veterinary medicinal product as they apply to all medicinal products under this Law, or any provision made under it, subject to such exceptions, adaptations and modifications as the context requires or as the appropriate Department may, by order, prescribe.

(2) Without prejudice to subsection (1), the provisions of sections 66(1) to (4) (Labelling and marketing of containers and packages), 67(1) and (2) (Leaflets) and 68 (Requirements as to containers) shall have effect in relation to animal feeding stuffs in which veterinary medicinal products have been incorporated as if in those provisions any reference to veterinary medicinal products were a reference to animal feeding stuffs in which veterinary medicinal products have been incorporated.

Offences under Part V and certain provisions of this Part in relation to veterinary medicinal products.

105. (1) Subject to sections 124 (Contravention due to default of other person) and 125 (Warranty as defence), any person who contravenes the provisions of section 66(5) (Labelling and marking of containers and packages), 67(3) or (4) (leaflets) or 94(2) (Provisions as to medicated feeding stuffs), shall be guilty of an offence and liable -

(a) on summary conviction, to a fine not exceeding level 3 on the uniform scale,

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

(2) Any regulations made under this Part, may provide that any person who contravenes the regulations, or who contravenes the provisions of section 66(3), 67(2) or 68(2) (Requirements as to containers), or any of those provisions as applied by section 94(1), shall be guilty of an offence and -

(a) shall be liable on summary conviction to a fine not exceeding level 3 on the uniform scale or such lesser sum as may be specified in the regulations, and

(b) if the regulations so provide, shall be liable on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both.

(3) Without prejudice to the application of section 132 (Ordinances, orders and regulations), any power to make regulations conferred by sections 66 to 68, may be exercised so as to impose requirements either in relation to medicinal products generally or in relation to medicinal products of a particular description, or falling within a particular class, specified in the regulations, and any power to make regulations conferred by those sections as applied by section 94(1) (Provisions as to medicated animal feeding stuffs) shall be similarly construed.

(4) In this Part, "**requirements**" includes restrictions.

Application of Part VI of this Law to veterinary medicinal products.

106. The provisions of Part VI (Promotion of sales of veterinary medicinal products) apply to any veterinary medicinal product as they apply to all medicinal products under this Law, or any provision made under it, subject to such exceptions, adaptations and modifications as the context requires or as the appropriate Department may, by order, prescribe.

Application of Part VIII of this Law to veterinary medicinal products.

107. (1) The provisions of Part VIII (Miscellaneous and supplementary provisions) apply to any veterinary medicinal product as they apply to all medicinal products under this Law, or any provision made under it, subject to such exceptions, adaptations and modifications as the context requires or as the appropriate Department may, by order, prescribe.

(2) The appropriate Department may by Ordinance make further provisions as it considers necessary or expedient, in relation to the regulation of veterinary medicinal products.

PART VIII
MISCELLANEOUS AND SUPPLEMENTARY PROVISIONS

Application of Law to certain articles and substances.

108. (1) The Department may by order specify any description or class of articles or substances appearing to them to be articles or substances which are not medicinal products but are manufactured, sold, supplied, imported or exported for use wholly or partly for a medicinal purpose, and may by the order direct that, subject to such exceptions and modifications as may be specified in the order, such provisions, or any regulations made under paragraph 12 of Schedule 2 in respect of clinical trials, 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.

Application of Law to certain other substances which are not medicinal products.

109. (1) The Department may by order specify any substance appearing to the Department to be a substance which is not itself a medicinal product but -

(a) is used as an ingredient in the manufacture of medicinal products, or

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

and direct that, subject to such exceptions and modifications as may be specified in the order, such provisions, or any regulations made under paragraph 12 of Schedule 2 in respect of clinical trials as may be so specified (including any provisions so

specified which relate to offences or penalties) shall have effect in relation to that substance as those provisions have effect in relation to medicinal products.

(2) The power conferred by subsection (1) may be exercised in relation to a class of substances if it appears to the Department that the conditions specified in paragraph (a) or paragraph (b) of that subsection are fulfilled in relation to all substances falling within that class.

(3) No order shall be made under this section -

(a) in relation to a substance as being a substance in respect of which the condition specified in subsection (1)(b) is fulfilled, or

(b) in relation to a class of substances as being substances in respect of which that condition is fulfilled.

Regulation of poisons.

110. The appropriate Department may by order make provision for the regulation of any substance that appears, to the appropriate Department, to be a poison.

Extension of references to carrying on business.

111. (1) The Department may by order direct that such provisions, as may be specified in the order, in so far as they relate to things done by a person in the course of a business carried on by him, shall have effect, subject to such exceptions and modifications as may be specified in the order, as if in those provisions any reference to a business included a reference to an activity (other than a business) of a description specified in the order.

(2) Without prejudice to subsection (1), the Department may by order direct that such provisions, as may be specified in the order, in so far as they

relate to things done by a person in the course of a business carried on by him, shall have effect, subject to such exceptions and modifications as may be specified in the order, as if, in such circumstances as may be so specified, a business carried on by a person's employer were a business carried on by that person.

Validity of decisions and related proceedings.

112. (1) Except as provided by the following provisions, the validity of any decision of the regulatory authority under Part II (Regulatory provisions relating to medicinal products) , or of the Department under section 56 (Registration of premises), and the validity of any licence, authorisation or certificate recognised, granted or issued (as the case may be) or other thing done in pursuance of any such decision, shall not be questioned in any legal proceedings.

(2) If the person to whom such a decision relates desires to question the validity of the decision on the grounds -

(a) that it is not within the powers, or

(b) that any of the requirements of, or any regulations made under this Law, which are applicable to the matter to which the decision relates, have not been complied with,

that person may, at any time within the period of three months from the date on which notice of the decision is served on him, make an application to the Royal Court under this section.

(3) On any application under this section the Royal Court -

(a) may, by interim order, suspend the operation of the decision to which the application relates until the final determination of the proceedings,

(b) if satisfied that the decision is not within its powers, or that the interests of the person making the application have been substantially prejudiced by a failure to comply with any of the requirements mentioned in subsection (2)(b), may quash the decision.

(4) Where a decision to recognise or grant a licence, recognition or certificate is quashed under this section, any licence, recognition or certificate granted in pursuance of that decision shall be void, and any proceedings on the application for the grant of the licence, authorisation or certificate may be continued as if no such decision had been made.

Enforcement in the Bailiwick and appointment of Chief Inspector.

113. (1) The Department shall appoint the Chief Pharmacist as the Chief Inspector.

(2) It shall be the duty of the Chief Inspector to enforce, or to secure the enforcement in the Bailiwick of, the provisions of this Law, and any regulations and orders made under it.

(3) Subject to subsection (5), the appropriate Department may, in consultation with the Chief Inspector, appoint additional inspectors to assist the Chief Inspector with the performance of his duty under subsection (2).

(4) For the avoidance of doubt, the powers under this Law of -

(a) the Chief Inspector, and

(b) any additional inspectors appointed under subsection (3),

are in addition to and not in derogation from the power of Her Majesty's Procureur, and any police or customs officer, to secure the enforcement in the Bailiwick of the provisions of this Law, and any regulations and orders made under it.

(5) Any additional inspectors appointed under subsection (3) shall either be -

(a) qualified as pharmacists in accordance with the Doctors, Dentists and Pharmacists Ordinance, 1987,

(b) representatives of the MHRA who have been approved in writing by the Department, or

(c) shall be qualified veterinary surgeons or persons with relevant experience of animal husbandry.

(6) The Chief Inspector and any additional inspectors shall hold office in accordance with such conditions as the Department may determine.

Certain inspectors appointed under section 113(3) to notify appropriate Department.

114. An inspector who is appointed under section 113(3) by virtue of qualification for such appointment under section 113(5)(b), may exercise the powers of entry, powers of inspection and power to take samples under sections 115 (Rights of entry) and 116 (Power to inspect, take samples and seize goods and documents), as if he were an inspector appointed under that section by virtue of qualification for such appointment under sections 113(5)(a) or (c) if, and only if -

(a) the inspector has informed the appropriate Department of his desire to exercise the powers,

(b) the appropriate Department has authorised the inspector in writing that he may exercise the powers,

(c) a representative of the appropriate Department (or an inspector appointed under section 113(3), by virtue of qualification for such appointment under section 113(5)(a) or (c)), accompanies the inspector when he exercises the powers, and

(d) the inspector -

(i) reports any findings obtained, and

(ii) provides any samples taken,

to the appropriate Department and the Chief Inspector.

Rights of entry.

115. (1) Subject to the following provisions, any inspector appointed under section 113(3), by virtue of qualification for such appointment under section 113(5)(a) or (c), (Enforcement in the Bailiwick and appointment of Chief Inspector) shall, on production, if required, of his credentials, have a right at any reasonable time to enter any premises -

(a) for the purpose of ascertaining whether there is or has been, on or in connection with those premises, any contravention of any provisions, or of any regulations or order made under this Law,

(b) generally for the purposes of the performance by the appropriate Department of their functions under this Law or under any such regulations or order, or

(c) for any other purpose as the appropriate Department may specify, by order

(2) Any inspector appointed under section 113(3) (Enforcement in the Bailiwick and appointment of Chief Inspector), by virtue of qualification for such appointment under section 113(5)(a) or (c) shall, on production, if required, of his credentials, have a right at any reasonable time -

(a) to enter any ship or aircraft for the purpose of ascertaining whether there is in the ship or aircraft any substance or article imported in contravention of any provisions, or of any regulations or order made under this Law, and

(b) to enter any 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) Without prejudice to subsection (1), any inspector appointed under section 113 shall, on production, if required, of his credentials, have a right at any reasonable time to enter any premises occupied by an applicant for a licence or certificate under Part II (Regulatory provisions relating to medicinal products), for the purpose of verifying any statement contained in the application for the licence or certificate.

(4) Admission to any premises used only as a private dwelling-house shall not be demanded as of right by virtue of the preceding provisions unless twenty-four hours' notice of the intended entry has been given to the occupier.

(5) If the Bailiff on sworn information in writing, is satisfied that there are reasonable grounds for entering any premises for any purpose for which an inspector appointed under section 113(3) (Enforcement in the Bailiwick and appointment of Chief Inspector), by virtue of qualification for such appointment under section 113(5)(a) and (c), has a right to enter them in accordance with the preceding provisions, 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,

(b) that an application for admission, or the giving of such a notice, would defeat the object of the entry,

(c) that the case is one of urgency, or

(d) that the premises are unoccupied or the occupier is temporarily absent,

the Bailiff may by warrant under his hand authorise the appropriate Department, or any such inspector, to enter the premises, if need be by force.

(6) Subsection (5) shall have effect in relation to entering any ship, aircraft, vehicle, stall or place which may be entered under subsection (2) section as it has effect in relation to entering any premises, as if in the last preceding subsection any reference to the occupier were a reference to the master, commander or other person in charge of the ship, aircraft, vehicle, stall or place.

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

(8) In this section -

"**home-going ship**" means a ship engaged exclusively in coastal voyages, and

"**coastal voyage**" means a voyage which starts and ends in the Bailiwick and does not involve calling at any place outside the Bailiwick.

Power to inspect, take samples and seize goods and documents.

116. (1) For the purpose of ascertaining whether there is or has been a contravention of this Law, or of any regulations or order made thereunder, any inspector appointed under section 113(3), by virtue of qualification for such appointment under section 113(5)(a) and (c) (Enforcement in the Bailiwick and appointment of Chief Inspector), shall have a right to inspect -

(a) any substance or article appearing to him to be a medicinal product,

(b) any article appearing to him to be a container or package used or intended to be used to contain any medicinal product or to be a label or leaflet used or intended to be used in connection with a medicinal product, or

(c) any plant or equipment appearing to him to be used or intended to be used in connection with the manufacture or assembly of medicinal products, and any process of manufacture or assembly of any medicinal products and the means employed, at any stage in the processes of manufacture or assembly, for testing the materials after they have been subjected to those processes.

(2) Where for the purpose specified in subsection (1) an inspector so authorised 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 inspector so authorised as mentioned in that subsection shall have a right -

(a) to require any person carrying on a business which consists of or includes the manufacture, assembly, sale or supply of medicinal products, and any person employed in connection with such a business, to produce any books or documents relating to the business which are in his possession or under his control,

(b) to take copies of, or of any entry in, any book or document produced in pursuance of the preceding paragraph.

(4) Any inspector so authorised shall have a right to seize and detain any substance or article which he has reasonable cause to believe to be a substance or article in relation to which, or by means of which, an offence under this Law is being or has been committed, and any document which he has

reasonable cause to believe to be a document which may be required as evidence in proceedings under this Law.

(5) For the purpose of exercising any such right as is specified in subsection (4), the person having that right may, so far as is reasonably necessary in order to secure that the provisions, and any regulations or order made thereunder are duly observed, require any person having authority to do so to break open any container or package or open any vending machine, or to permit him to do so.

(6) Where a person seizes any substance or article (including any document) in the exercise of such a right as is specified in subsection (4), he shall inform the person from whom it is seized, and, in the case of anything seized from a vending machine, the person whose name and address are stated on the machine as being those of the owner of the machine, or, if no name and address are so stated, the occupier of the premises on which the machine stands or to which it is affixed.

(7) Without prejudice to the preceding provisions, any inspector appointed under section 113(3) (Enforcement in the Bailiwick and appointment of Chief Inspector), by virtue of qualification for such appointment under section 113(5)(a) or (c), shall have the rights conferred by those provisions in relation to things belonging to, or any business carried on by, an applicant for a licence or certificate under Part II, and may exercise those rights for the purpose of verifying any statement contained in the application for the licence or certificate; and, where by virtue of this subsection a person exercises any such right as is specified in subsection (4), he shall be subject to the duty imposed by subsection (6).

(8) Notwithstanding anything in the preceding provisions, where a person claiming to exercise a right by virtue of this Law 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 4 to this Law shall have effect with respect to samples obtained on behalf of enforcement authorities for the purposes of this Law.

Application of sampling procedure to substance or article seized under section 116.

117. (1) The provisions of this section shall have effect where an inspector appointed under section 113(3) (Enforcement in the Bailiwick and appointment of Chief Inspector), by virtue of qualification for such appointment under section 113(5)(a) or (c) (in this section referred to as an "**authorised officer**"), seizes a substance or article (other than a document) in the exercise of such a right as is specified in section 116(4) (Power to inspect, take samples and seize goods and documents), (including that section as applied by section 116(7)).

(2) If any person who in accordance with section 116(6) is entitled to be informed of the seizure so requests, either at the time of the seizure or at any subsequent time, not being later than twenty-one days after he is informed of the seizure, then, subject to subsection (3), the authorised officer shall either -

(a) set aside a sample of the substance or article seized, or

(b) treat that substance or article as a sample,

whichever he considers more appropriate having regard to the nature of that substance or article.

(3) An authorised officer shall not be required by virtue of subsection (2) 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 officer sets aside a sample, or treats a substance or article as a sample, he shall divide it into three parts, each part to be marked and sealed or fastened up in such manner as its nature will permit, and shall supply one part of it to the person who made the request under subsection (2).

(5) Paragraphs 10, 11 and 12 and 15 to 27 of Schedule 4 (Sampling) shall have effect in relation to a sample set aside, or a substance or article treated as a sample, in accordance with subsection (2) as they have effect in relation to a sample obtained as mentioned in paragraph 1 of that Schedule, but as if in those paragraphs -

(a) any reference to a sampling officer were a reference to an authorised officer,

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

(c) any reference to the preceding provisions of that Schedule were a reference to the preceding provisions of this section, and

(d) any reference to the relevant enforcement authority were a reference to the authority by whom the authorised officer is authorised for the purposes of section 116 (Power to inspect, take samples and seize goods and documents),

and as if in paragraph 24(1) of that Schedule the reference to a substance or article obtained as mentioned in paragraph 1 of that Schedule were a reference to a substance or article of which a sample has been set aside, or which has been treated as a sample, in accordance with subsection (2).

Supplementary provisions as to rights of entry and related rights.

118. (1) Any person entering any property (that is to say, any premises, ship, aircraft, vehicle, stall or place) by virtue of section 115 (Rights of entry), (whether in pursuance of a warrant or not) may take with him such other persons and such equipment as may appear to him to be necessary; and on leaving any such property which he has entered in pursuance of a warrant under that section he shall, if the property is unoccupied or the occupier (or, in the case of a ship, aircraft, vehicle, stall or place, the master, commander or other person in charge of it) is temporarily absent, leave it as effectively secured against trespass as he found it.

(2) Any person who -

(a) wilfully obstructs a person acting in pursuance and duly authorised so to act by an enforcement authority,

(b) wilfully fails to comply with any requirement properly made to him by a person so acting under section 113, 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 Law,

shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding level 3 on the uniform scale.

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

(a) on summary conviction, to a fine not exceeding level 3 on the uniform scale,

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

(4) Nothing in this section shall be construed as requiring a person to answer any question or give any information if to do so might incriminate that person or, where that person is married, the spouse of that person.

Analysis of samples in other cases.

119. (1) A person who, not being a person authorised in that behalf by the appropriate Department, has purchased a medicinal product may submit a sample of it for analysis to the States analyst.

(2) Paragraphs 2 to 13 of Schedule 4 (Sampling) shall have effect in relation to a person proposing to submit a sample in pursuance of subsection (1), as if in those paragraphs any reference to the sampling officer were a reference to that person.

(3) Subject to the following provisions, the States analyst to whom a sample is submitted under subsection (1) shall as soon as practicable analyse the sample or cause it to be analysed by some other person under his direction.

(4) If the States analyst to whom a sample is submitted under subsection (1) determines that for any reason an effective analysis of the sample cannot be performed by him or under his direction, he shall as soon as practicable cause it to be analysed by some other appropriately qualified person outside the Bailiwick.

(5) The States analyst to whom a sample is submitted or sent under this section may demand payment in advance of the prescribed fee, and, if he demands such payment, he shall not be required to analyse the sample or cause it to be analysed until the fee has been paid.

(6) The States analyst who has analysed a sample or caused a sample to be analysed under this section shall issue a certificate specifying the result of the analysis to the person by whom the sample was originally submitted.

(7) Any certificate issued under subsection (6) shall be in a form prescribed by the appropriate Department and shall be signed by the States analyst who issues the certificate.

(8) Paragraphs 21 to 23 of Schedule 4 shall have effect in relation to a certificate issued under subsection (6) as they have effect in relation to a certificate issued under paragraph 19 of that Schedule.

(9) Any regulations prescribing a fee for the purposes of this section shall be made by the appropriate Department.

(10) In this section "**States analyst**" has the meaning given in paragraph 1(2) of Schedule 4 to this Law.

Facilities for microbiological examinations.

120. (1) The Department may provide facilities for microbiological examinations of drugs for the purpose of fulfilling any of the functions under this Law.

(2) The Department may, by order, prescribe facilities for microbiological examinations of drugs for the purpose of fulfilling any of the functions under this Law.

Liability to forfeiture under Customs and Excise Law 1972.

121. (1) For the purposes of section 22 of the Customs and Excise (Bailiwick of Guernsey) Law 1972 (Forfeiture of goods improperly imported) any imported goods shall be deemed to be imported contrary to a restriction for the time being in force with respect to them under this Law 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 30 of the Customs and Excise (Bailiwick of Guernsey) Law 1972 (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 Law 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 or are, or normally are, animal feeding stuffs in which medicinal products have been incorporated.

Restrictions on disclosure of information.

122. (1) If any person discloses to any other person -

(a) any information with respect to any manufacturing process or trade secret obtained by him in premises which he has entered by virtue of section 115 (Rights of entry), or

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

he shall, unless the disclosure was made in the performance of his duty, be guilty of an offence.

(2) Subsection (1) does not apply if -

(a) the person making the disclosure referred to in that section is, or is acting on behalf of a person who is the holder of a public office or is a public authority,

(b) the information is not held by the authority on behalf of another person.

(3) Any person guilty of an offence under this section shall be liable -

(a) on summary conviction, to a fine not exceeding level 3 on the uniform scale,

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

Protection for officers of Department and inspectors.

123. (1) An officer of the appropriate Department or an inspector appointed by the Department under section 113(3), by virtue of qualification for such appointment under section 113(5)(a) or (c), (Enforcement in the Bailiwick and appointment of Chief Inspector) shall not be personally liable in respect of any act done by him in the execution or purported execution of this Law, and within the scope of his employment if he did it in the honest belief that his duty under this Law required or entitled him to do it.

(2) Where an action has been brought against an officer of the appropriate Department in respect of an act done by him in the execution or purported execution of this Law, and the circumstances are such that he is not legally entitled to require the enforcement authority to indemnify him, the authority may nevertheless indemnify him against the whole or part of the damages and costs or expenses which he may have been ordered to pay or may have incurred, if they are satisfied that he honestly believed that his duty under this Law required or entitled him to do it.

(3) In this section any reference to an officer of the appropriate Department shall be construed as including a reference to any person who, not being an officer of the authority, is authorised to act in pursuance of this Law, by such an authority; and in relation to any such person any reference in this section to the scope of his employment shall be construed as a reference to the scope of the authorisation under which he acts.

Contravention due to default of other person.

124. (1) Where a contravention by any person of any provision to which this section applies constitutes an offence under this Law, 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 Law 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 seven clear days before the date of the hearing, he has served on the prosecutor a notice in writing giving such information identifying, or assisting in the identification of, the other person in question as was then in his possession.

(4) This section applies to the following provisions, that is to say, sections 40 (Adulteration of medicinal products) to 42 (Compliance with standards specified in monographs in certain publications), 66 (Labelling and marketing of containers and packages) to 94 (Provisions as to medicated feeding stuffs) and 73 (False or misleading advertisements and representations) to 76 (Advertisements and representations directed to practitioners), and the provisions of any regulations made under any of those sections.

Warranty as defence.

125. (1) Subject to the following provisions, in any proceedings for an offence under this Law 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 Bailiwick as being a substance or article which could be lawfully sold, supplied, or offered or exposed for sale, or could be lawfully sold, supplied, or offered or exposed for sale under the name or description or for the purpose under or for which he sold, supplied or offered or exposed it for sale, and with a written warranty to that effect,

(b) that at the time of the commission of the alleged offence he had no reason to believe that it was otherwise, and

(c) that the substance or article was then in the same state as when he purchased it.

(2) This section applies to the following provisions, that is to say, sections 40(b) (Adulteration of medicinal products), 41 (Protection of purchasers of medicinal products), 42 (Compliance with standards specified in monographs in certain publications), 66 (Labelling and marketing of containers and packages) to 69 (Distinctive colours, shapes and markings of medicinal products) and 94 (Provisions as to medicated feeding stuffs) and the provisions of any regulations made under any of those sections.

(3) A warranty shall not be a defence by virtue of this section unless the defendant has, not later than three clear days before the date of the hearing, sent to the prosecutor a copy of the warranty with a notice stating that he

intends to rely on it and specifying the name and address of the person from whom he received it, and has also sent a like notice to that person.

(4) Where the defendant is a servant of the person who purchased the substance or article under the warranty, he shall be entitled to rely on the provisions 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.

Offences in relation to warranties and certificates of analysis.

126. (1) If a defendant in any such proceedings as are mentioned in section 125(1) (Warranty as defence) wilfully applies to any substance or article -

(a) a warranty given in relation to a different substance or article, or

(b) a certificate issued under section 119 (Analysis of samples in other cases), or under paragraph 19 of Schedule 4 (Sampling) to this Law, which relates to a sample of a different substance or article,

he shall be guilty of an offence.

(2) A person who, in respect of any substance or article sold by him in respect of which a warranty might be pleaded under section 125, gives to the purchaser a false warranty in writing, shall be guilty of an offence, unless he proves that when he gave the warranty he had reason to believe that the statement or description contained in it was accurate.

(3) Where the defendant in any such proceedings as are mentioned in section 125(1), relies successfully on a warranty given to him or to his employer, any proceedings for an offence under subsection (2) may, at the option of the prosecutor, be taken either before a court having jurisdiction in the place where a sample of the substance or article to which the warranty relates was procured, or before a court having jurisdiction in the place where the warranty was given.

(4) Any person guilty of an offence under this section shall be liable -

(a) on summary conviction, to a fine not exceeding level 3 on the uniform scale,

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

Offence by body corporate.

127. (1) Where an offence under this Law which is committed by a body corporate is proved to have been committed with the consent and connivance of, or to be attributable to any neglect on the part of, any director, manager, secretary or other similar officer of the body corporate, or any person who was purporting to Law in any such capacity, he as well as the body corporate shall be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

(2) In relation to a body corporate carrying on a retail pharmacy business as mentioned in section 51(1), subsection (1) shall have effect in relation to a person who (not being such an officer of the body corporate as is mentioned in subsection (1)) -

(a) is the superintendent referred to in section 51(1), or

(b) at any premises where the business is carried on, is the pharmacist referred to in section 51(1)(a) who acts under the directions of the superintendent,

as if he were such an officer of the body corporate as is mentioned in the preceding subsection.

(3) In this section "**director**", in relation to a body corporate established by or under any enactment for the purpose of carrying on under national ownership any industry or part of an industry or undertaking, being a body corporate whose affairs are managed by its members, means a member of that body corporate.

Presumptions.

128. (1) For the purposes of any proceedings under this Law for an offence consisting of -

(a) offering any animal feeding stuff for sale in contravention of section 93 (Medicated feeding stuffs),

(b) offering a medicinal product for sale by retail in contravention of section 29 (Sale or supply of medicinal products not on general sale list) or 30 (Sale or supply of medicinal products on general sale list), or

(c) offering a medicinal product for sale in contravention of section 40(b) (Adulteration of medicinal products),

where it is proved that the animal feeding stuff or medicinal product in question was found on a vehicle from which animal feeding stuffs or medicinal products are sold, it shall be presumed, unless the contrary is proved, that the person in charge of the vehicle offered that animal feeding stuff or medicinal product for sale and, in a case falling within paragraph (b), that he offered it for sale by retail.

(2) For the purposes of any proceedings under this Law for an offence consisting of a contravention of so much of any provision to which this subsection applies as relates to a person's having any medicinal product or animal feeding stuff in his possession for the purpose of sale or supply, where it is proved that the medicinal product or animal feeding stuff 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 or of animal feeding stuffs in which medicinal products have been incorporated, it shall be presumed, unless the contrary is proved, that he had that medicinal product or animal feeding stuff in his possession for the purpose of sale or supply.

(3) Subsection (2) applies to the following provisions, that is to say, sections 40(b), 66(3) and (5) (Labelling and marking of containers and packages), 68(2) (Requirements as to containers) and 69(3) (Distinctive colours, shapes and markings of medicinal products) and to any of those provisions as applied by sections 93(1) and (2) (Provisions as to medicated feeding stuffs) except in so far as they relate to leaflets.

(4) For the purposes of any proceedings under this Law for an offence consisting of a contravention of sections 67 (2) or (3) (Leaflets), or of so much of section 93(2) as relates to leaflets, 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 or of animal feeding stuffs in which medicinal products have been incorporated, it shall be presumed, unless the contrary is proved, that he had the leaflet in his possession -

(a) where the offence charged relates to section 85 (Medicinal tests on animals), for the purpose of supplying it with a medicinal product, or

(b) where the offence charged relates to section 94 (Provisions as to medicated animal feeding stuffs), for the purpose of supplying it with animal feeding stuffs in which a medicinal product has been incorporated.

Service of documents.

129. Without prejudice to section 49 (Service of notice), any notice or other document required or authorised by any provision, to be served on any person, or to be given or sent to any person, may be served, given or sent -

(a) by delivering it to him,

(b) by sending it by post to him at his usual or last-known residence or place of business in the Bailiwick, or

(c) in the case of a body corporate, by delivering it to the secretary or clerk of the body corporate at its registered or principal office or sending it by post to the secretary or clerk of that body corporate at that office.

Financial provisions.

130. (1) Any expenses incurred in consequence of this Law, by the appropriate Department, shall be defrayed out of monies provided by the States.

(2) Any fees and other sums received by virtue of this Law shall be paid to the appropriate Department.

Power to amend Law by Ordinance.

131. (1) The States may by Ordinance amend this Law.

(2) Subsection (1) is without prejudice to any other provision of this Law conferring power to enact Ordinances or orders or regulations (and vice versa).

(3) An Ordinance under this section does not have effect in Alderney or Sark unless approved by the States of Alderney or (as the case may be) by the Chief Pleas of Sark.

(4) For the purposes of subsection (3), an Ordinance shall be deemed to have been approved by the States of Alderney, or the Chief Pleas of Sark, at the expiration of a period of four months immediately following the day of its approval by the States of Deliberation unless, within that period -

(a) the States of Alderney resolve to disapprove its application to Alderney or, as the case may be,

(b) the Chief Pleas of Sark resolve to disapprove its application to Sark.

Ordinances, orders and regulations.

132. (1) An Ordinance, order or regulation under this Law -

(a) may be amended or repealed by a subsequent Ordinance, order or (as the case may be) regulation made hereunder,

(b) may contain such consequential, incidental, supplementary and transitional provision as may appear to be necessary or expedient, and

(c) may contain provision making consequential amendments to this Law.

(2) Any power conferred by this Law to make any Ordinance, order or regulations may be exercised -

(a) in relation to all cases to which the power extends, or in relation to all those cases subject to specified exceptions, or in relation to any specified cases or classes of cases,

(b) so as to make, as respects the cases in relation to which it is exercised -

(i) the full provision to which the power extends, or any lesser provision (whether by way of exception or otherwise),

(ii) the same provision for all cases, or different provision for different cases or classes of cases, or different provision for the same case or class of case for different purposes,

(iii) any such provision either unconditionally or

subject to any prescribed conditions.

Meaning of "medicinal product" and related expressions.

133. (1) Subject to the following provisions, in this Law -

"**medicinal product**" means -

(a) any substance, or article (not being an instrument, apparatus or appliance) or combination of substances presented as having properties for treating or preventing disease in human beings, or

(b) any substance, or article (not being an instrument, apparatus or appliance) or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis,

"**substance**" means any matter irrespective of origin which may be -

(a) any human matter prescribed by the Department, by order,

(b) animal, e.g. micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products,

(c) vegetable, e.g. micro-organisms, plants, parts of plants, vegetable secretions, extracts, or

(d) chemical, e.g. elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis.

(2) In this Law a "**medicinal purpose**" means any one or more of the following purposes, that is to say -

(a) treating or preventing disease,

(b) diagnosing disease or ascertaining the existence, degree or extent of a physiological condition,

(c) contraception,

(d) inducing anaesthesia, or

(e) otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating, reducing or postponing, or increasing or accelerating, the operation of that function or in any other way.

(3) An order made by the Department may provide that, for the purposes of this Law, any specified description or class of medicated feeding stuff -

(a) is to be treated as a medicinal product (subject to the following provisions), or

(b) is not to be so treated (notwithstanding anything in subsection (1)).

(4) In subsection (3) "**medicated feeding stuff**" means any substance which is manufactured, sold, supplied, imported or exported for use wholly or mainly in either or both of the following ways, that is to say -

(a) use by being fed to one or more animals for a medicinal purpose or for purposes that include that purpose, or

(b) use as an ingredient in the preparation of a substance which is to be fed to one or more animals for a medicinal purpose or for purposes that include that purpose.

(5) In this Law "**medicinal product**" does not include -

(a) whole human blood and human blood components (unless the Department prescribes otherwise in relation to paragraph (a) of the definition of "substance" under subsection (1)),

(b) substances and articles of such other descriptions or classes as may be specified by an order made by the appropriate Department for the purposes of this subsection.

(6) For the purposes of this Law, "**human blood component**" means any of the following constituents of human blood: red cells, white cells, platelets and plasma.

(7) In this Law "**administer**" means administer to a human being or an animal, whether orally, by injection or by introduction into the body in any other way, or by external application, whether by direct contact with the body or

not; and any reference in this Law to administering or feeding a substance or article is a reference to administering or feeding it either in its existing state or after it has been dissolved or dispersed in, or diluted or mixed with, some other substance used as a vehicle.

(8) For the purposes of this Law, a document, advertisement or representation shall be taken to be likely to mislead as to the uses or effects of medicinal products of a particular description if it is likely to mislead as to any of the following matters, that is to say -

(a) any purposes for which medicinal products of that description can with reasonable safety be used,

(b) any purposes for which such products cannot be so used, and

(c) any effect which such products when used, or when used in any particular way referred to in the document, advertisement or representation, produce or are intended to produce.

Meaning of "wholesale dealing", "retail sale" and related expressions.

134. (1) In this Law any reference to selling anything by way of wholesale dealing is a reference to selling it to a person as being a person who buys it for one or more of the purposes specified in subsection (2), except that it does not include any such sale by the person who manufactured it.

(2) The purposes referred to in the preceding subsection, in relation to a person to whom anything is sold, are the purposes of -

(a) selling or supplying it, or

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

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

(3) In this Law any reference to selling by retail, or to retail sale, is a reference to selling a substance or article to a person as being a person who buys it otherwise than for a purpose specified in subsection (2).

(4) In this Law 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 a purpose other than that of -

(a) selling or supplying it, or

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

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

(5) For the purposes of this Law the provision of services by or on behalf of the Department shall be treated as the carrying on of a business by that Department.

Repeals.

135. The enactments listed in Schedule 5 are repealed.

General interpretation provisions.

136. (1) In this Law unless the context requires otherwise, the following words and expressions shall be construed in accordance with this

subsection or the other provisions of this Law referred to in relation to them in this subsection -

"**the Agency**" means the European Medicines Agency established by Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency,

"**analysis**" includes micro-biological assay but no other form of biological assay, and "analyse" has a corresponding meaning,

"**animal**" means any living creature except man,

"**animal feeding stuff**" means any substance which is intended for use either by being fed to one or more animals or as an ingredient in the preparation of such a substance, not being in either case a medicinal product,

"**animal test certificate**" : see section 85(2(b),

"**the appropriate committee**" **:** see section 4(7),

"**the appropriate department**" : see section 1(b),

"**assemble**" in relation to a medicinal product, means enclosing the product (with or without other medicinal products of the same description) in a container which is labelled before the product is sold or supplied, or, where the product (with or without other medicinal products of the same description) is already enclosed in the container in which it is to be sold or supplied, labelling the container before the product is sold or supplied in it, and "assembly" has a corresponding meaning,

"**authorised veterinary medicinal product**" : see section 81,

"**the Bailiff**" means -

(a) as respects the Islands of Guernsey, Herm and Jethou, the Bailiff,

(b) as respects the Island of Alderney, the Chairman of the Court of Alderney,

(c) as respects the Island of Sark, the Seneschal of Sark,

"**business**" includes a professional practice and includes any activity carried on by a body of persons, whether corporate or unincorporate,

"**the Chief Inspector**" means the Chief Pharmacist or, if he is unavailable, a nominee of the Chief Officer of the Department,

"**Chief Pharmacist**" means the person appointed as chief pharmacist by the Department,

"**the Committee**" means the Medicines Committee established under this Law,

"**composition**" in relation to a medicinal product, means the ingredients of which it consists and the proportions, and the degrees of strength, quality and purity, in which those ingredients are contained in it respectively,

"**container**" in relation to a medicinal product, means the bottle, jar, box, packet or other receptacle which contains or is to contain it, not being a capsule, cachet or other article in which the product is or is to be

administered, and where any such receptacle is or is to be contained in another such receptacle, includes the former but does not include the latter receptacle,

"**contravention**" includes failure to comply and "contravene" has a corresponding meaning,

"**customs officer**" means an officer within the meaning of section 1(1) of the Customs and Excise (General Provisions) (Bailiwick of Guernsey) Law, 1972[s],

"**the Department**" shall be construed in accordance with section 1,

"**dentist**" means a person registered in the dentists register under the the Doctors, Dentists and Pharmacists Ordinance, 1987[t],

"**the 2001 Directive**" means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use, as amended, from time to time,

"**disease**" includes any injury, ailment or adverse condition, whether of body or mind,

"**district or community nurse**" means a person who is registered in the Nurses: Sub-Part 1, of the new register established by the Nurses and Midwives (Parts of and Entries in the Register) Order of Council 2004 (UK Statutory Instrument No. 1765), maintained by the Nursing and Midwifery Council,

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s Ordres en Conseil Vol. XXIII, p. 573; Vol XXIV, P. 87; Vol. XXXI, p. 278; No. XIII of 1991; No. X of 2004 and Ordinance No. XXXII of 2004.

t Recueil d'Ordonnances Tome XXIV, pp.79, 238 and 262.

"**doctor**" means a registered medical practitioner within the meaning of the Doctors, Dentists and Pharmacists Ordinance, 1987[u] ,

"**document**" includes information stored or recorded in any form (including, without limitation, in electronic form); and, in relation to information stored or recorded otherwise than in legible form, references to its production, however expressed, include (without limitation) references to the production of the information in a form -

(a) in which it can be taken away, and

(b) in which it is visible and legible or from which it can readily be produced in a visible and legible form,

"**EEA State**" means a Member State, Norway, Iceland or Liechtenstein,

"**electronic form**", in relation to the storage or recording of documents, includes storage or recording by means of any form of information storage technology,

"**enactment**" includes any subordinate legislation and any Directive or Regulation of any of the institutions of the European Union,

"**enforcement authority**" : see section 113,

"**export**" means export from the Bailiwick, whether by land, sea or air, and "import" has a corresponding meaning,

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[u] Recueil d'Ordonnances Tome XXIV, pp.79, 238 and 262.

"**the first appointed day**" has the meaning assigned to it by section 16(1),

"**the Gazette**" means La Gazette Official published in the Bailiwick,

"**general sale list**" : see section 28,

"**health visitor**" means a person who is registered in the Specialist Community Public Health Nurses part of the new register established by the Nurses and Midwives (Parts of and Entries in the Register) Order of Council 2004 (UK Statutory Instrument No. 1765), maintained by the Nursing and Midwifery Council,

"**herbal remedy**" means a medicinal product consisting of a substance produced by subjecting a plant or plants to drying, crushing or any other process, or of a mixture whose sole ingredients are two or more substances so produced, or of a mixture whose sole ingredients are one or more substances so produced and water or some other inert substance,

"**herd**" includes a flock,

"**Her Majesty's Procureur**" includes Her Majesty's Comptroller,

"**homoeopathic medicinal product**": see section 7,

"**hospital**" means any hospital registered by or operated by the Department,

"**ingredient**", in relation to the manufacture or preparation of a substance, includes anything which is the sole active ingredient of that substance as manufactured or prepared,

"investigational medicinal product": see section 8,

"labelling", in relation to a container or package of medicinal products, means affixing to or otherwise displaying on it a notice describing or otherwise relating to the contents, and "label" has a corresponding meaning,

"**leaflet**" includes any written information,

"**licence**" means a wholesale dealer's licence and/or a manufacturer's licence,

"**manufacture**" in relation to a medicinal product, includes any process carried out in the course of making the product, but does not include dissolving or dispersing the product in, or diluting or mixing it with, some other substance used as a vehicle for the purpose of administering it and does not include the incorporation of the product in any animal feeding stuff,

"**manufacturer's licence**" : see section 8(2),

"**marketing authorisation**" means an authorisation granted by the Agency, the MHRA, or the Secretary of State,

"**medicinal product**" **:** see section 133(1),

"**medicinal purpose**" : see section 133(2),

"**medicinal test on animals**" has the meaning assigned to it by section 85,

"**the MHRA**" means the Medicines and Healthcare products Regulatory Agency of Her Majesty's Government in right and title of the

United Kingdom responsible for ensuring that medicines and medicinal products work and are safe,

"**nurse prescriber**" means a person who is registered either in the Nurses: Sub-part 1, Midwives, or Specialist Community Public Health Nurses parts of the new register established by the Nurses and Midwives (Parts of and Entries in the Register) Order of Council 2004 (UK Statutory Instrument No. 1765), maintained by the Nursing and Midwifery Council,

"**Nursing and Midwifery Council**" means the Nursing and Midwifery Council established by the Nursing and Midwifery Order 2001, (UK Statutory Instrument No. 253),

"**offence under this Law**" includes an offence under any Ordinance, regulations or order made under this Law,

"**package**" in relation to any medicinal products, means any box, packet or other article in which one or more containers of the products are or are to be enclosed, and, where any such box, packet or other article is or is to be itself enclosed in one or more other boxes, packets or other articles, includes each of the boxes, packets or articles in question,

"**Pharmaceutical Society**" means the Royal Pharmaceutical Society of Great Britain,

"**pharmacy registrar**" : see section 47,

"**plant**" includes any part of a plant,

"**poison**" means any substance or other thing specified as such by the appropriate Department, by order,

"**police officer**" means -

(a) in relation to Guernsey, Herm and Jethou -

(i) a member of the salaried police force of the Island of Guernsey, and

(ii) within the limits of his jurisdiction, a member of the special constabulary of the Island of Guernsey,

(b) in relation to Alderney -

(i) a member of the salaried police force of the Island of Guernsey,

(ii) a member of any police force which may be established by the States of Alderney, and

(iii) within the limits of his jurisdiction, a member of the Alderney Special Constabulary appointed pursuant to section 47 of the Government of Alderney Law, 2004[v], and

(c) in relation to Sark -

(i) the Constable,

(ii) the Vingtenier, and

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[v] Order in Council No. III of 2004.

(iii) a member of the salaried police force of the Island of Guernsey,

"**poultry**" means domestic fowls, turkeys, geese, ducks, guinea-fowls, pigeons, pheasants and partridges,

"**practitioner**" (except where that word occurs as part of the expression "veterinary practitioner") means a doctor, dentist or veterinary surgeon,

"**prescribed**" means prescribed by regulations or any Ordinance or order under this Law,

"proprietary medicinal product": see section 8,

"radiopharmaceutical": see section 7,

"**recognised licence**" means either a wholesale dealer's licence or manufacturer's licence recognised in accordance with regulations made under section 7(3) and cognate expressions shall be construed accordingly,

"**recognised marketing authorisation**" means a marketing authorisation recognised in accordance with regulations made under section 7(3) and cognate expressions shall be construed accordingly,

"**recognition**" means a recognised licence and/or recognised marketing authorisation, as the case may be,

"**registered pharmacy**" has the meaning given to it by section 55,

"**the regulatory authority**" : see section 6,

"**retail pharmacy business**" means a business (not being a professional practice carried on by a practitioner) which consists of or includes the retail sale of medicinal products other than medicinal products on a general sale list (whether medicinal products on such a list are sold in the course of that business or not),

"**retail sale**" : see section 134,

"**the Royal Court**" means the Royal Court of Guernsey sitting as an Ordinary Court,

"Secretary of State" means a United Kingdom Minister designated for the purposes of making United Kingdom regulations under section 2(2) of the European Communities Act 1972[w] in relation to measures in the veterinary and phytosanitory fields for the protection of public health,

"**States analyst**" : see Schedule 4,

"**States veterinarian**" means the States veterinary officer, appointed by the States of Guernsey,

"**substance**" means any natural or artificial substance, whether in solid or liquid form or in the form of a gas or vapour,

"**the time allowed",** in Part II this Law has the meaning given to it by paragraph 4(12) of Schedule 2,

"**treatment",** in relation to disease, includes anything done or provided for alleviating the effects of the disease, whether it is done or provided by way of cure or not,

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[w] An Act of Parliament (1972 c.68).

"**uniform scale**" means the uniform scale of fines from time to time specified under the Uniform Scale of Fines (Bailiwick of Guernsey) Law, 1989[x],

"**United Kingdom**" means the United Kingdom of Great Britain and Northern Ireland,

"**veterinary medicinal product**": see section 78,

"**veterinary medicines registrar**" : see section 93(12),

"**veterinary surgeon**" means a person authorised to practise in the Islands of Guernsey and Alderney under the Veterinary Surgery and Animal Welfare Ordinance, 1987[y],

"**wholesale dealing**" : see section 134,

"**wholesale dealer's licence**" : see section (8)(7), and

"**writing**" includes any form of notation, whether by hand or by printing, typewriting, electronic or any similar process, and "**written**" has a corresponding meaning.

(2) For the purposes of this Law, "**considerations of safety**", in relation to any substance or article, shall be taken to include consideration of the extent (if any) to which the substance or article -

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[x] Ordres en Conseil Vol. XXXI, p. 278.

[y] Recueil d'Ordonnances Tome No XXIV, p.51 (applied to Alderney by Ordinance of the States of Alderney No XVIII, 1994).

(a) 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,

(b) if administered to an animal, may be harmful to the animal or may induce disease in other animals or may leave a residue in the carcase or produce of the animal which may be harmful to human beings,

(c) may interfere with the treatment, prevention or diagnosis of disease, or

(d) may be harmful to the person administering it or (in the case of an instrument, apparatus or appliance) the person operating it,

and any reference in this Law to safety or to the interests of safety shall be construed accordingly.

(3) In this Law any reference to doing anything in accordance with a licence under Part II, shall be construed as a reference to doing it in pursuance of such a licence and in compliance with any conditions and any limitations (whether as to area or otherwise) to which the licence is subject, and so as to not to fall within any exceptions to which it is subject, and any reference to doing anything in accordance with. an animal test certificate shall be construed in a corresponding way.

(4) Any reference in this Law to the holder of a licence, certificate or authorisation shall be construed as a reference to the holder of a licence, certificate or authorisation which is for the time being in force.

(5) For the purposes of this Law, medicinal products of any description shall be taken to be effectively on the market in the Bailiwick at a particular time if (but only if) during the whole of the period of one month ending with that time adequate stocks of medicinal products of that description were available, or could within a reasonable time be made available, for sale or supply to such persons in the Bailiwick as were likely to require them.

(6) Unless the context requires otherwise, any reference in this Law to an enactment shall be construed as a reference to that enactment as, from time to time amended or extended by or under any other enactment, including this Law.

(7) Words and expressions importing the masculine gender include the feminine and a body corporate.

(8) The Interpretation (Guernsey) Law, 1948[z] applies to the interpretation of this Law throughout the Bailiwick.

Citation and commencement.

137. (1) This Law may be cited as the Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008.

(2) This Law shall come into operation on such date as the States may by Ordinance appoint; and different dates may be appointed for different provisions and for different purposes.

S.M. SIMMONDS,
Her Majesty's Deputy Greffier.

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[z] Ordres en Conseil Vol. XIII, p. 355.

SCHEDULE 1

PROVISIONS RELATING TO COMMITTEE AND SUB-COMMITTEES

Section 5

Co-opted members.

1. (1) Subject to the approval of the appropriate Department, at any meeting of the Committee or a sub-committee, the Committee or sub-committee may co-opt additional members.

(2) A co-opted member shall hold office only in relation to the meeting for which he is co-opted.

Delegation of functions by Committee and subcommittee.

2. (1) Subject to subparagraph (2), the Committee or any sub-committee may, with the consent of the appropriate Department, delegate to an appropriate expert such of its functions as it thinks fit.

(2) Subject to subparagraph (3), a Committee or any sub-committee may not delegate any function which consists of advising the regulatory authority in cases where the regulatory authority is required to consult that Committee or sub-committee pursuant to the provisions of -

(a) Part II,

(b) any regulations made under paragraph 12 of Schedule 2 in respect of clinical trials,

(3) The Committee or sub-committee may arrange for an appropriate expert to provide advice or assistance in relation to the performance of any function referred to in subparagraph (2) of this paragraph.

Terms of office of members.

3. The appropriate Department may make provision by regulations with respect to one or more of the following matters -

(a) the terms on which members of the Committee or any sub-committee shall hold and vacate office, including the terms on which any person appointed as chairman of such a committee shall hold and vacate office as chairman, and

(b) the terms on which members of the Committee or any sub-committee shall hold and vacate office, including the terms on which any person appointed as chairman of such a Group shall hold and vacate office as chairman.

Staff, premises and facilities.

4. The appropriate Department shall provide the Committee or any sub-committee established under section 4, with such staff and such accommodation, services and other facilities as appear to the Department to be necessary or expedient for the proper performance of their functions.

Validity of proceedings.

5. The validity of any proceedings of the Committee or any sub-committee established under section 4, shall not be affected by -

(a) a vacancy among the members of that the Committee or any sub-committee, or

(b) a defect in the appointment of any member of that the Committee or any sub-committee.

Proceedings.

6. (1) The Committee or any sub-committee may, subject to approval by the appropriate Department, make such provision as it thinks fit to regulate its own proceedings.

(2) Any sub-committee established under section 4, shall have the power to regulate their procedure.

Remuneration and expenses of members.

7. The approrpiate Department may pay to the members of the Committee or any sub-committee and of any further sub-committee established under section 4, such remuneration (if any) and such allowances as may be determined by the appropriate Department with the consent of the States.

Expenses of experts.

8. The appropriate Department shall defray any expenses incurred with their approval by the Committee or any sub-committee or by any sub-committee established under section 4.

Status.

9. No sub-committee or any further sub-committee established under section 4 shall be taken to be the servant or agent of the States whilst the members of those sub-committees are carrying out their functions under this Law.

SCHEDULE 2

APPLICATIONS FOR RECOGNITION, GRANT AND RENEWAL OF LICENCES

Section 18

Applications for recognition, grant and renewal of, licences

Application for licence or recognition.

1. (1) A person who wishes to obtain a licence, or recognition of a licence relating to medicinal products, shall make application by delivering to the Department -

(a) an application and

(b) such documents, samples, and other materials or information,

in such form, as may be specified by order of the Department made under this paragraph.

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

Factors relevant to determination of application for licence (or recognition).

2. (1) Subject to the following provisions of this Schedule, in dealing with an application for a licence, or recognition of a licence, the regulatory authority shall take into consideration -

(a) the efficacy of medicinal products of each description to which the application relates for the purposes for

which the products are proposed to be administered, (disregarding any question as to whether medicinal products of another description would or might be equally or more efficacious for that purpose),

(b) the safety of medicinal products of each such description (and, in considering this, may take into account whether medicinal products of another description, being equally or more efficacious for that purpose, would or might be safer in relation to that purpose),

(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, and

(d) whether the products of each such description are authorised veterinary medicinal products.

(2) Where any such application indicates that the purposes for which the licence, or recognition of a 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 regulatory authority shall also take into consideration in particular the methods, standards and conditions of manufacture of those products and may, if they think fit, require the production by the applicant of any one or more of the following -

(a) an undertaking, given by the manufacturer of any such products, to permit -

(i) the premises where they are or are to be manufactured, and

(ii) the operations carried on or to be carried on in the course of manufacturing them,

to be inspected by or on behalf of the regulatory authority,

(b) an undertaking, given by or on behalf of the manufacturer of any such products, to comply with any prescribed conditions or with any other conditions that may be attached to the licence or recognition of a licence by the regulatory authority, or

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

(3) Where any such application indicates that the purposes for which the licence, or recognition of a licence, is required relate exclusively to the exportation of medicinal products, the regulatory authority shall disregard considerations of safety and efficacy (as mentioned in subparagraph (1)(a) and (b)) if satisfied that in the circumstances it is reasonable to do so.

(4) In dealing with an application for a manufacturer's licence, or recognition of a manufacturer's licence, the regulatory authority shall in particular take into consideration -

(a) the operations proposed to be carried out in pursuance of the licence, or recognition 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 -

(i) the safekeeping of, and

(ii) the maintenance of,

adequate records in respect of medicinal products manufactured or assembled under the licence, or recognised licence.

(5) In dealing with an application for a wholesale dealer's licence, or recognition of a wholesale dealer’s licence, the regulatory 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 products from those premises, and

(d) the arrangements made or to be made for securing -

(i) the safekeeping of, and

(ii) the maintenance of adequate records in respect of, medicinal products stored on or distributed from those premises.

Grant or refusal of licence, or recognition of licence.

3. (1) Subject to section 8(6) and (11) (Provisions as to manfacture and wholesale dealing) and paragraph 2 (Factors relevant to determination of application for licence), and to the following provisions, on any application to the regulatory authority for a licence under this Schedule, the regulatory authority, acting on the advice of the Committee -

(a) may grant a licence containing such provisions and subject to such conditions as they consider appropriate, or

(b) may refuse to grant a licence, if they consider it necessary or expedient to do so, having regard to any relevant provision including any provision of any enactment or reasons of public policy,

(c) where they decide to refuse to grant a licence, or decide to grant a licence otherwise than in accordance with the application, shall inform the applicant of their reasons for so doing.

(2) The regulatory authority must either grant or refuse any application for a licence, or recognition of a licence, under this Schedule and Part II, before the end of a period of 90 days from the date upon which it receives the application.

(3) If there are requirements in force under paragraph 1 (application for licence or recognition) that apply to the application, sub paragraph (2) applies only if the requirements have been met.

(4) If a notice under section 20 (provision of information to regulatory authority) requires the applicant to provide the regulatory authority with information, the period specified in subparagraph (2) stops running when the notice is given, and does not start running again until -

(a) the regulatory authority receives the information, or

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

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

(6) The regulatory authority shall not refuse to grant or recognise a licence on any grounds relating to the safety, quality or efficacy of medicinal

products of any description, except after consultation with the Committee and, if the Committee considers it appropriate, any relevant sub-committee.

Procedure on reference to the Committee.

4. (1) Where the Committee are consulted under paragraph 3 (Grant or refusal of licence, or recognition of a licence) and are of the provisional opinion that, on grounds relating to safety, quality or efficacy, they -

(a) may be unable to advise the regulatory authority to grant, or recognise, the licence, or

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

they shall notify the applicant accordingly.

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

(3) The Committee shall give the applicant an opportunity to make such representations in accordance with subparagraphs (4) to (7).

(4) Subject to subparagraph (5), the applicant shall provide the Committee with -

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

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

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

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

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

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

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

(9) The Committee shall -

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

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

(10) After receiving the report of the Committee, the regulatory authority shall -

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

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

(c) notify the applicant of the decision made.

(11) Once the regulatory authority have -

(a) notified the applicant of any decision to refuse to grant the licence or recognition, or to grant it otherwise than in accordance with the application, and

(b) of the reasons for that decision,

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

(12) In this Schedule, "**the time allowed**" means the period of twenty-eight days beginning with the date of the relevant notification, or such longer period as the regulatory authority may allow in any particular case.

Procedure in other cases.

5. (1) This paragraph applies when -

(a) an application is made for the grant of a licence under this Schedule, and

(b) the appropriate committee -

(i) is not consulted under paragraph 3(6) (grant or refusal of licence or recognition of a licence) or

(ii) is consulted under that subparagraph but does not give a provisional opinion in accordance with paragraph 4(1) (Procedure on reference to Committee).

(2) If the regulatory authority propose -

(a) to refuse to grant the licence or recognition, or

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

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

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

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

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

(4) If the applicant makes written representations in accordance with subparagraph (3)(b), the regulatory authority shall take those representations into account before determining the application.

Hearing before person appointed.

6. (1) If the applicant gives notice under paragraph 4(11) (Procedure on reference to Committee) or paragraph 5(3) (Procedure in other cases) of his wish to appear before and be heard by a person appointed by the regulatory authority, the authority shall -

(a) make that appointment, and

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

(2) The person appointed -

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

(i) the Committee,

(ii) any of its sub-committees established under section 4, and

(b) shall not be an officer or servant of the States.

(3) Subject to subparagraph (4), the applicant shall provide the person appointed with -

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

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

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

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

(5) If the applicant fails to comply with the time limit in subparagraph (3), or, with any extended time limit granted under subparagraph (4), -

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

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

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

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

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

(9) After the hearing -

(a) the person appointed shall provide a report to the regulatory authority, and

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

(10) The regulatory authority shall then -

(a) notify the applicant of their decision,

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

Special provisions as to effect of manufacturer's licence.

7. (1) Subject to the provisions of this Schedule and Part VII, relating to medicinal tests on animals and to the following provisions, a manufacturer's licence does not permit 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 marketing authorisation which is applicable to medicinal products of that description, or

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

(i) a person who is the holder of such a marketing authorisation, or

(ii) where the Department has made any regulations under paragraph 12 concerning clinical trials, if the products are to be used for the purposes of any clinical trial, the sponsor of that trial,

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

(2) Subject to subparagraph (3), subparagraph (1) shall not have effect in relation to the manufacture or assembly of any medicinal product to the order of a practitioner, where the practitioner -

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

(b) being a veterinary surgeon, 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, for administration to an animal or herd which is under the care of that other veterinary surgeon, or

(c) is a pharmacist whose order is in accordance with a prescription given by a practitioner.

(3) The exemption conferred by subparagraph (2)(a) in a case falling within, or which relates to subparagraph 2(b) or (c), does not apply to a vaccine specially prepared for administration to poultry.

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

(5) Where subparagraph (1) 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, be deemed to be not in accordance with that licence.

(6) In this paragraph -

"**clinical trial**" means any investigation in human subjects, other than a non-interventional trial, intended -

(a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products,

(b) to identify any adverse reactions to one or more such products, or

(c) to study absorption, distribution, metabolism and excretion of one or more such products,

and which is carried out only after the appropriate department has taken advice from the Department’s ethics committee, and

"**sponsor**" means, in relation to a clinical trial, the person who takes responsibility for the initiation, management and financing (or arranging the financing) of that trial.

Duration and renewal of licence.

8. (1) A licence granted or recognised under this Schedule expires -

(a) in accordance with the provisions of the licence or recognition, or

(b) if there is no such provision, at the end of the period of five years beginning with the date on which the licence was granted, or if it has been renewed, the date on which it was last renewed.

(2) But so far as the licence or recognition relates to a medicinal product to which the 2001 Directive applies, it remains in force until -

(a) revoked by the regulatory authority, or

(b) surrendered by the holder.

(3) Where any licence has been granted or recognised under this Schedule, and the regulatory authority subsequently consider that it would no longer be possible to grant that licence or recognition without contravening any enactment, the regulatory authority may serve a notice on the holder of the licence specifying a date when the licence or recognition shall expire.

(4) Any licence granted or recognised under this Schedule, if it has not been revoked, may, on the application of the holder of the licence, be renewed by the regulatory 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 regulatory authority may determine.

(5) Subparagraph (4) does not apply to a licence insofar as it relates to a medicinal product to which the 2001 Directive applies.

(6) On an application to the regulatory authority for the renewal of a licence or recognised licence under this Schedule, the regulatory authority -

(a) may renew the licence or recognised licence, with or without modifications, for such a further period as is mentioned in subparagraph (4), or

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

(c) if, having regard to the provisions, and any provision under the 2001 Directive other than Titles VI, VII and VIII of that Directive, they consider it necessary or expedient to do so, may refuse to renew the licence or recognition or to grant a new licence or recognition.

(7) References to a licence, or recognition in subparagraph (6) are to be read as references to a licence only insofar as that licence or recognition relates to a medicinal product to which the 2001 Directive does not apply.

(8) In relation to any such application the provisions of paragraphs 1 (application for licence or recognition) and 2 (factors relevant to determination of application for licence), paragraph 3(1)(c), (5) and (6) (grant or refusal of licence or recognition of a licence) and paragraphs 4 to 6, shall have effect as if in those provisions any reference to refusing a licence or recognition

included a reference to refusing to renew a licence or recognition and any reference to granting a licence or recognition included a reference to renewing it.

(9) Every application for the grant or renewal of a licence or recognition shall, unless it otherwise expressly provides, be taken to be an application for the grant or renewal of the licence or recognition for the full period of five years mentioned in subparagraph (1) or (4), as the case may be; and in this Schedule and Part II, any reference (including a reference implied by virtue of subparagraph (8)) to the grant or renewal of a licence or recognition otherwise than in accordance with the application shall be construed accordingly.

(10) Subparagraph (9) does not apply to a licence or recognition insofar as it relates to a medicinal product to which the 2001 Directive applies.

(11) Where an application for the renewal of a licence or recognition under this Law has been duly made -

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

(b) if by an interim order made under section 112(3)(a), the operation of the decision of the regulatory authority on the application is suspended, the licence or recognition 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 or recognised licences

General power to suspend, revoke or vary licences.

9. (1) Subject to the following provisions of this Schedule, the regulatory authority may, after taking the advice of the Committee, suspend a licence under this Part, for such period as the authority may determine, or may revoke, or vary the provisions of, any such licence or recognition.

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

(3) Subject to subparagraph (4) the powers conferred by this paragraph shall not be exercisable by the regulatory authority in relation to a recognised marketing authorisation except on one or more of the following grounds -

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

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

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

(d) that the holder of the licence or recognition has without reasonable excuse failed to comply with a requirement imposed on him under section 20(2), to furnish information to the regulatory 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, that the holder of the licence or recognised licence has not, within two years after the grant of the licence or recognition, notified to the regulatory 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 Bailiwick,

(g) that medicinal products of any description to which the licence or recognition relates can no longer be regarded as products which can safely be administered for the purposes indicated in the licence or recognition, 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 or recognition, insofar as they relate to the incorporation in animal feeding stuffs of any medicinal product are not in accordance with any relevant provision of any enactment, or

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

(i) are made under section 66, (Labelling and marking of containers and packages),

(ii) impose requirements which give effect to any relevant provisions of any enactment, or

(iii) impose requirements which give effect to any other provisions or guidance which the regulatory authority considers relevant,

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

(4) Where a marketing authorisation relates to a product to which the 2001 Directive applies, the power conferred by this paragraph to suspend a licence or recognition shall be exercisable in relation to the licence or recognition on the ground that -

(a) any of the provisions contained in regulations made under section 66 (Labelling and marking of containers and packages) or 67 (Leaflets), or

(b) section 67(4),

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

(5) Subject to the following provisions, the powers conferred by this paragraph shall not be exercisable in relation to a manufacturer's licence or a wholesale dealer's licence or recognition 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 or recognition 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 or recognition has to a material extent been contravened by the holder of the licence or recognition,

(d) that the holder of the licence or recognition has without reasonable excuse failed to comply with a requirement imposed on him under section 20(2), to furnish information to the regulatory authority with respect to medicinal products of a description to which the licence or recognition relates.

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

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

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

(7) In relation to a wholesale dealer's licence or recognition, the powers conferred by this paragraph shall be exercisable on the following grounds, in addition to those specified in subparagraph (5), that is to say, that the equipment and facilities for storing or distributing medicinal products which are available to the holder of the licence or recognition are inadequate to maintain the quality of medicinal products of one or more descriptions to which the application for the licence related.

(8) The preceding provisions have effect subject to the next paragraph.

Procedure where regulatory authority propose to suspend, revoke or vary licence or recognition under paragraph 9.

10. (1) The provisions of Schedule 3 to this Law shall have effect where the regulatory authority propose to exercise any power conferred by paragraph 9.

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

Variation of licence or recognition on application of holder.

11. (1) Where the holder of a licence or recognition under this Schedule applies to the regulatory authority for the licence to be varied, the following provisions apply.

(2) The application must -

(a) be in writing,

(b) specify the required variation,

(c) be signed by or on behalf of the applicant,

(d) be accompanied by such information as is reasonably required to enable the regulatory authority to consider the application,

(e) if there is a requirement in force under this Law or any other enactment made thereunder to pay a fee in respect of the application, be accompanied by the required fee.

(3) The regulatory authority must consider any application properly made under this paragraph.

(4) If subparagraph (5) applies, they must either vary the licence or recognition or refuse to vary it before the end of the period allowed for considering the application.

(5) This subparagraph applies to a variation which would have the effect of altering -

(a) the types of medicinal product,

(b) any operation carried out under the licence,

(c) any premises, or

(d) any equipment or facilities,

in respect of which the licence or recognition was granted.

(6) If the regulatory authority considers that it is necessary for them to conduct an inspection of any premises to which the application relates, the period allowed is 90 days beginning with the date on which they receive the application.

(7) Otherwise, the period allowed is 90 days beginning with that date.

(8) The regulatory authority may give the applicant written notice requiring him to give them such further information in connection with the application as they consider reasonable.

(9) The period allowed for consideration stops running when a notice is given under subparagraph (8) and does not start running again until -

(a) the regulatory authority receives the information, or

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

(10) Nothing in this paragraph affects the powers conferred by paragraph 9.

Clinical trials in respect of medicines for human use.

12. (1) The Department may make regulations concerning the carrying out of clinical trials in respect of medicines for human use.

(2) Any regulations made under subparagraph (1) may, without limitation include provision for the designation of certain medicinal products as investigational medicinal products.

Interpretation and power to amend by order.

13. (1) In this Schedule, references to a recognised licence, recognition or recognition of a licence include reference to a recognised marketing authorisation.

(2) The Department may amend the provisions of this Schedule, by order.

SCHEDULE 3

SUSPENSION, REVOCATION OR VARIATION OF LICENCE

Section 18

Procedure on consultation with appropriate committee.

1. Subject to paragraph 8, where the regulatory authority proposes, in the exercise of its powers under paragraph 9 of Schedule 2, -

(a) to suspend, revoke or vary a recognised marketing authorisation on the grounds specified in paragraph 9(3)(a) or (c) of that Schedule, in a case where it appears to the regulatory authority that the matters or characteristics in question are such as to affect the safety, efficacy or quality of medicinal products to which the recognition relates, or

(b) to suspend, revoke or vary a recognised marketing authorisation on any of the grounds specified in paragraph 9(3)(g) or (h) of that Schedule,

the regulatory authority shall not suspend, revoke or vary the recognition except after consultation with the appropriate committee.

2. (1) Where the appropriate committee are consulted under paragraph 1 and are of the provisional opinion that, on such grounds as are mentioned in that paragraph, they may have to advise the regulatory authority that the marketing authorisation ought to be revoked, varied or suspended, the appropriate committee shall notify the holder of the recognition accordingly.

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

(3) The appropriate committee shall give the holder of the recognition an opportunity to make such representations in accordance with subparagraphs (4) to (7).

(4) Subject to subparagraph (5), the holder of the recognition shall provide the appropriate committee with -

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

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

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

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

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

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

(8) The appropriate committee shall -

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

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

3. (1) After receiving the report of the appropriate committee the regulatory authority shall -

(a) decide whether to continue with the proposal to revoke, vary or suspend the recognised marketing authorisation, and

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

(2) The regulatory authority shall then notify the holder of the recognition of -

(a) the decision made pursuant to subparagraph (1), and

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

4. If -

(a) the appropriate committee was consulted under paragraph 1,

(b) the committee did not give a provisional opinion under paragraph 2(1), and

(c) the regulatory authority propose -

(i) to determine the matter in a way which differs from the advice of the committee, or

(ii) to suspend, revoke or vary the recognition on grounds not relating to safety, quality or efficacy,

the authority shall notify the holder of the recognition accordingly.

(2) A notification given under subparagraph (1) shall state -

(a) the advice of the committee and the reasons stated by the committee for that advice, and

(b) the proposals of the regulatory authority and the reasons for them.

5. (1) Subject to subparagraph (4), a person to whom a notification has been given under paragraph 3(2) may, within the time allowed, notify the regulatory authority that he wishes to appear before and be heard by a person appointed by the regulatory authority with respect to the decision.

(2) A person to whom a notification has been given under paragraph 4(1) may, within the time allowed -

(a) notify the regulatory authority that he wishes to appear before and be heard by a person appointed for the purpose by the regulatory authority, or

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

(3) If the applicant makes written representations in accordance with subparagraph (2)(b), the regulatory authority shall take those representations into account before determining the matter.

(4) Subparagraph (1) shall not apply where -

(a) the person has not made any representations in accordance with paragraph 2(4) to (7), and

(b) the decision of the regulatory authority was in accordance with the advice of the appropriate committee.

Procedure in other cases.

6. (1) This paragraph applies where the regulatory authority propose, in the exercise of the powers conferred by paragraph 9 of Schedule 2 -

(a) to suspend, revoke or vary a licence or recognition under Part 2, other than a recognised marketing authorisation, or

(b) to suspend, revoke or vary a recognised marketing authorisation where the holder of the recognition has been given neither -

(i) notice of any provisional opinion or any advice of the appropriate committee which led to that proposal under paragraphs 2 and 3, nor

(ii) notice of that proposal under paragraph 4,

and the provisions of paragraph 8 do not apply.

(2) The regulatory authority shall notify the holder of the licence or recognition of -

(a) their proposals,

(b) the reasons for them, and

(c) the date (not being earlier than twenty-eight days from the date of the notification) on which it is proposed that the suspension, revocation or variation should take effect.

(3) The holder of the licence or recognition may, before the date specified in the notification -

(a) notify the regulatory authority of his wish to appear before and be heard by a person appointed by the regulatory authority with respect to the decision, or

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

(4) If the applicant makes written representations in accordance with subparagraph (3)(b), the regulatory authority shall take those representations into account before determining the matter.

Hearing before person appointed.

7. (1) If the holder of the licence or recognition gives notice under paragraph 5 or 6 of his wish to appear before and be heard by a person appointed by the regulatory authority, the authority shall -

(a) make that appointment, and

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

(2) The person appointed -

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

(i) the Committee established under section 2, or any of its sub-committees, or

(ii) a sub-committee or any other committee established under section 4,, and

(b) shall not be an officer or servant of the States.

(3) Subject to subparagraph (4), the holder of the licence or recognition shall provide the person appointed with -

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

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

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

(4) If the holder of the licence or recognition so requests, the person appointed may, after consulting the regulatory authority, extend the time limit referred to in subparagraph (3), up to a maximum period of six months beginning with the date of the notice referred to in subparagraph (1).

(5) If the holder of the licence or recognition fails to comply with the time limit in subparagraph (3), or, where he has been granted an extended time limit under subparagraph (4), that time limit -

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

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

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

(7) At the hearing before the person appointed, both the holder of the licence or recognition and the regulatory authority may make representations.

(8) If the holder of the licence or recognition so requests the hearing shall be in public.

(9) After the hearing -

(a) the person appointed shall provide a report to the regulatory authority, and

(b) the regulatory authority shall take this report into account and decide whether to revoke, vary or suspend the licence or recognition.

(10) The regulatory authority shall then -

(a) notify the holder of the licence or recognition of their decision,

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

Procedure in cases of urgency.

8. Notwithstanding anything in paragraphs 1 to 7, where it appears to the regulatory authority that in the interests of safety it is necessary to suspend a licence or recognition under Part 2, with immediate effect, the regulatory authority may do so, for a period not exceeding three months.

9. If the licence is a recognised marketing authorisation, the regulatory authority shall report the suspension forthwith to the appropriate committee.

10. If, after the suspension has taken effect -

(a) it appears to the regulatory authority; or

(b) in the case of a recognised marketing authorisation, the regulatory authority is advised by the appropriate committee,

that it is necessary to consider whether the licence or recognition ought to be further suspended, or ought to be revoked or varied, the regulatory authority (subject to paragraph 11) shall proceed in accordance with such of the provisions of paragraphs 1 to 7 as are applicable in the circumstances.

11. (1) This paragraph applies where, in the circumstances specified in paragraph 10, the regulatory authority proceed as mentioned in that paragraph and any proceedings under paragraphs 1 to 7 relating to a further suspension of the licence or recognition have not been finally disposed of before the end of the period -

(a) for which the licence or recognition was suspended under paragraph 8 of this Schedule, or

(b) for which it has been further suspended under this paragraph.

(2) If it appears to the regulatory authority to be necessary in the interests of safety to do so, the authority may further suspend the licence or recognition for a period which (in the case of each such further suspension) shall not exceed three months.

Interpretation.

12. In this Schedule, the "**the time allowed**" means the period of twenty-eight days from the date of the relevant notification, or such longer period as the regulatory authority may allow in any particular case.

SCHEDULE 4
SAMPLING

Section 116, 117 and 119

Introductory.

1. (1) The provisions of this Schedule have effect where a person authorised by the enforcement authority (in this Schedule referred to as a "**sampling officer**") obtains a sample of any substance or article -

(a) for the purpose of ascertaining whether there is or has been, in connection with that substance or article, any contravention of any provisions of this Law, or of any Ordinance or subordinate legislation made thereunder, or

(b) otherwise for any purpose connected with the performance by that authority of its functions under this Law,

and the sampling officer obtains the sample by purchase or in the exercise of any power conferred by section 116.

(2) In this Schedule "States analyst" means the person appointed to that position by the States of Guernsey.

Division of sample.

2. The sampling officer shall forthwith divide the sample into three parts, each part to be marked and sealed or fastened up in such manner as its nature will permit.

3. If the sample was purchased by the sampling officer, otherwise than from an automatic machine, he shall supply one part of the sample to the seller.

4. If the sampling officer obtained the sample from an automatic machine, then -

(a) if a person's name, and an address in the Bailiwick, 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 Bailiwick and was taken by the sampling officer before delivery to the consignee, the sampling officer shall supply one part of the sample to the consignee.

6. If, in a case not falling within any of paragraphs 3 to 5, the sample was obtained by the sampling officer at the request or with the consent of a purchaser, the sampling officer shall supply one part of the sample to the seller.

7. If, in a case not falling within any of paragraphs 3 to 6, the sample was taken in transit, the sampling officer shall supply one part of the sample to the consignor.

8. In any case not falling within any of paragraphs 3 to 7 the sampling officer shall supply one part of the sample to the persons appearing to him to be the owner of the substance or article from which the sample was taken.

9. In every case falling within any of paragraphs 3 to 8 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 contents into parts -

(a) is not reasonably practicable, or

(b) might affect the composition or impede the proper analysis or other examination of the contents,

the sampling officer may divide the sample into parts by dividing the containers into three lots without opening them.

12. Section 129, shall have effect in relation to supplying any part of a sample in pursuance of the preceding paragraphs as it has effect in relation to the service of a document.

13. If after reasonable inquiry the sampling officer is unable to ascertain the name of a person to whom, or the address at which, a part of a sample ought to

be supplied in pursuance of the preceding paragraphs, he may retain that part of the sample instead of supplying it.

Notice to person named on container.

14. (1) Where it appears to the sampling officer that a substance or article of which he has obtained a sample was manufactured or assembled by a person whose name and address in the Bailiwick are stated on its container, and who is not a person to whom a part of the sample is required to be supplied under the preceding provisions of this Schedule, the sampling officer, unless he decides not to submit the sample for analysis or other appropriate examination, shall serve notice on that person -

(a) stating that the sample has been obtained by the sampling officer, and

(b) specifying the person from whom the sampling officer purchased it, or, if he obtained it otherwise than by purchase, the place from which he obtained it.

(2) The notice required to be served under subparagraph (1) shall be served before the end of the period of three days beginning with the day on which the sample was obtained.

Analysis or other examination of sample.

15. If the sampling officer decides to submit the sample for analysis or other appropriate examination, he shall -

(a) submit it for analysis to the States analyst,

(b) submit it for other appropriate examination to the person having the management or control of any laboratory available for the purpose in accordance with

any arrangements made in that behalf by the enforcement authority.

16. Any such arrangements as are mentioned in paragraph 15(b), if they relate exclusively to the examination or analysis of veterinary medicinal products in the Bailiwick shall be arrangements approved by the appropriate Department.

17. (1) Subject to subparagraph (2), the person to whom the sample is submitted under paragraph 15 shall analyse or examine the sample (as the case may be), or cause the sample to be analysed or examined by some other person under his direction, as soon as practicable.

(2) If the person to whom the sample is so submitted is the States analyst, and he determines that for any reason an effective analysis of the sample cannot be performed by him or under his direction, he shall send it to any other analyst approved by the Department for the purpose of this Schedule.

18. (1) The analyst who has analysed a sample submitted to him under the preceding provisions of this Schedule, or who has caused such a sample to be analysed by some other person under his direction, shall issue and send to the sampling officer a certificate specifying the result of the analysis.

(2) A person having the management or control of a laboratory in which a sample submitted to him under the preceding provisions of this Schedule has been analysed or examined, or a person appointed by him for the purpose, shall issue and send to the sampling officer a certificate specifying the result of the analysis or examination.

(3) Any certificate issued under this paragraph shall be in a form prescribed by the Department and shall be signed by the person who issues the certificate.

19. (1) Any person to whom, in accordance with paragraphs 2 to 8, a part of the sample is required to be supplied shall, on payment of the prescribed fee to the relevant enforcement authority, be entitled to be supplied with a copy of any certificate as to the result of an analysis or examination which is sent to the sampling officer under paragraph 18.

(2) Any regulations prescribing a fee for the purposes of this paragraph shall be made by the Department.

Provisions as to evidence.

20. In any proceedings for an offence under this Law a document produced by one of the parties to the proceedings and purporting to be a certificate issued under paragraph 18 shall be 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.

21. In any proceedings for an offence under this Law 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.

22. (1) If in any such proceedings before a magistrates' court a defendant intends to produce such a certificate, or to require that the person by whom such a certificate was issued shall be called as a witness, a notice of his intention, and (where he intends to produce such a certificate) a copy of the certificate, shall be given to the other party at least three clear days before the day on which the summons is returnable.

(2) If subparagraph (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.

23. (1) In any proceedings for an offence under this Law, 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 States analyst (or to be sent for other appropriate examination to the person having the management or control of a laboratory specified by the court.

(2) If, in a case where an appeal is brought, no action has been taken under subparagraph (1), the provisions of that subparagraph 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.

24. The costs of any analysis or examination under paragraph 23 shall be paid by the prosecutor or the defendant as the court may order.

Power to modify sampling provisions.

25. The Department may by order provide that, in relation to substances or articles of any such description as may be specified in the order, the preceding provisions of this Schedule shall have effect subject to such exceptions and modifications as may be specified in the order.

Payment for sample taken under compulsory powers.

26. (1) Where a sampling officer takes a sample in the exercise of any power conferred by section 116, 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 subparagraph (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 Royal Court.

Application of s 41 to samples.

27. Where a medicinal product is taken as a sample by a sampling officer in the exercise of any power conferred by section 116, the provisions of sections 41(1) to (4), shall have effect as if the taking of the product as a sample were a sale of it to the sampling officer by the person from whom it is taken; and, if the product was prepared in pursuance of a prescription given by a practitioner, those provisions shall so have effect as if, in subsection (1) of that section, for the words "demanded by the purchaser", there were substituted the words "specified in the prescription".

SCHEDULE 5

REPEALS

Section 131

1. The Pharmacists, Poisons and Pharmacy Ordinance, 1970, is repealed[aa].

2. The Penicillin and Allied Substances Ordinance 1950 is repealed[bb].

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aa Recueil d'Ordonnances Tome XVI, p. 236, as amended.

bb Recuiel d'Ordonnaces Tome X, p. 64.

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