Jersey

MEDICINES (JERSEY) LAW 1995

Official Consolidated Version

This is an official version of consolidated legislation compiled and issued under the authority of the Legislation (Jersey) Law 2021.

20.625

Showing the law from 28 September 2021 to Current

Jersey

MEDICINES (JERSEY) LAW 1995

Contents

Article

Jersey

MEDICINES (JERSEY) LAW 1995[1]

A LAW to make provision with respect to medicinal products and related matters, and for purposes connected therewith

Commencement [see endnotes]

PART 1

GENERAL

1 General interpretation

(1) In this Law unless the context otherwise requires –

"Advisory Council" means the Medicines Advisory Council established under Article 5;

"analysis" includes micro-biological assay but no other form of biological assay, and "analyse" has a corresponding meaning;

"animal" includes any bird, fish or reptile;

"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;

"appropriate practitioner" means a person of a description, or class, specified under Article 57(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;

"business" includes a professional practice and includes any activity carried on by a body of persons, whether corporate or unincorporate;

"certified midwife" means a person authorized to exercise the profession of midwife in Jersey under the Loi (1922) sur la Santé Publique (Sage-Femmes);

"clinical trial" and "clinical trial certificate" have the meanings assigned to them by Article 32;

"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 and Excise Law" means the Customs and Excise (Jersey) Law 1999;

"disease" includes any injury, ailment or adverse condition, whether of body or mind;

"doctor" means a person registered as a registered medical practitioner under the Medical Practitioners (Registration) (Jersey) Law 1960;

"enactment" includes an enactment of the United Kingdom;

"export" means export from Jersey, whether by land, sea or air, and "import" has a corresponding meaning;

"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 2 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;

"hospital" includes a clinic, nursing home or similar institution;

"hover vehicle" means a vehicle designed to be supported on a cushion of air;

"ingredient" in relation to the manufacture or preparation of a substance, includes anything which is the sole active ingredient of that substance as manufactured or prepared;

"labelling", in relation to a container or package of medicinal products, means affixing to or otherwise displaying on it a notice describing or otherwise relating to the contents, and "label" has a corresponding meaning;

"leaflet" includes any written information;

"licence of right" has the meaning assigned to it by Article 26;

"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;

"marketing authorization" means a marketing authorisation as defined by the Marketing Authorisations for Veterinary Medical Products Regulations 1994 of the United Kingdom or a marketing authorization as defined by the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 of the United Kingdom, both Regulations being Regulations made under section 2(2) of the European Communities Act 1972 of the United Kingdom;

"medicinal test on animals" has the meaning assigned to it by Article 33;

"Medicines Act" means the Medicines Act 1968 of the United Kingdom;

"Minister" means the Minister for Health and Social Services;

"offence under this Law" includes an offence under any Order made under this Law;

"Official Analyst" means the person appointed as such in pursuance of Article 2 of the Food Safety (Jersey) Law 1966;

"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;

"Poisons Law" means the Poisons (Jersey) Law 1952;

"plant" includes any part of a plant;

"poultry" means domestic fowls, turkeys, geese, ducks, guinea-fowls, pigeons, pheasants and partridges;

"practitioner" means a doctor, dentist or veterinary surgeon;

"prescribed" means prescribed by Order made under this Law;

"product licence", "manufacturer's licence" and "wholesale dealer's licence" have the meanings assigned to them by Articles 8 and 9;

"registered nurse" means a nurse registered as such in the professional register prepared and maintained in pursuance of the Nurses, Midwives and Health Visitors Act 1979 of the United Kingdom;

"registered pharmacy" has the meaning assigned to it by Article 73;

"retail pharmacy business" means a business (not being a professional practice carried on by a practitioner) which consists of or includes the retail sale of medicinal products other than medicinal products on a general sale list (whether medicinal products on such a list are sold in the course of that business or not);

"substance" means any natural or artificial substance, whether in solid or liquid form or in the form of a gas or vapour;

"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;

"United Kingdom product licence" means a licence granted for the purposes of section 7 of the Medicines Act of the United Kingdom;

"veterinary drug" means a medicinal product which is manufactured, sold, supplied, imported or exported for the purpose of being administered to animals, but not for the purpose of being administered to human beings;

"veterinary surgeon" means a person registered under the Veterinary Surgeons (Jersey) Law 1999.[2]

(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 –

(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 carcass 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) For the purposes of this Law medicinal products of any description shall be taken to be effectively on the market in Jersey at a particular time if at that time such products of that description were available, or could within a reasonable time be made available, for sale or supply to such persons in Jersey as were likely to require them.

(4) Unless the context otherwise requires, a reference in this Law to an enactment is a reference to that enactment as amended, applied or extended by or under any other enactment, including this Law.

2 Meaning of "medicinal product" and related expressions

(1) Subject to the following provisions of this Article in this Law "medicinal product" means any substance or article (not being an instrument, apparatus or appliance) which is manufactured, sold, supplied, imported or exported for use wholly or mainly in either or both of the following ways, that is to say –

(a) use by being administered to one or more human beings or animals for a medicinal purpose;

(b) use, in circumstances to which this paragraph applies, as an ingredient in the preparation of a substance or article which is to be administered to one or more human beings or animals for a medicinal purpose.

(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 and maintaining anaesthesia;

(e) otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating, reducing or postponing, or increasing or accelerating, the operation of that function or in any other way.

(3) In paragraph (1)(b) the reference to use in circumstances, to which that paragraph applies is a reference to any one or more of the following, that is to say –

(a) use in a pharmacy or in a hospital;

(b) use by a practitioner;

(c) use in the course of a business which consists of or includes the retail sale, or the supply in circumstances corresponding to retail sale, of herbal remedies.

(4) An Order made by the Minister 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 of this Article); or

(b) is not to be so treated (notwithstanding anything in paragraph (1)).

(5) In paragraph (4) "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.

(6) Notwithstanding anything in paragraphs (1) or (4), in this Law "medicinal product" does not include any substance or article which is manufactured for use wholly or mainly by being administered to one or more human beings or animals, where it is to be administered to them –

(a) in the course of the business of the person who has manufactured it (in this paragraph referred to as the "manufacturer"), or on behalf

of the manufacturer in the course of the business of a laboratory or research establishment carried on by another person;

(b) solely by way of a test for ascertaining what effects it has when so administered; and

(c) in circumstances where the manufacturer has no knowledge of any evidence that those effects are likely to be beneficial to those human beings, or beneficial to, or otherwise advantageous in relation to, those animals, as the case may be,

and which (having been so manufactured) is not sold, supplied or exported for use wholly or mainly in any way not fulfilling all the conditions specified in sub-paragraphs (a) to (c).

(7) In this Law "medicinal product" shall also be taken not to include –

(a) bandages and other surgical dressings, except medicated dressings where the medication has a curative function which is not limited to sterilizing the dressing;

(b) substances and articles of such other descriptions or classes as may be prescribed.

(8) Subject to paragraph (9), where in accordance with the foregoing provisions of this Article a substance or article is a medicinal product immediately after it has been manufactured, imported or exported as mentioned in paragraph (1) or immediately after the first occasion on which it has been sold or supplied as mentioned in that paragraph, then, it shall not cease to be a medicinal product for the purposes of this Law by reason only that, at any subsequent time, it is sold, supplied, imported or exported for use wholly or mainly in a way other than those specified in paragraph (1).

(9) For the purposes of this Law medicinal products are of the same description if (but only if) –

(a) they are manufactured to the same specification; and

(b) they are, or are to be, sold, supplied, imported or exported in the same pharmaceutical form,

and in this Law "description", in relation to medicinal products, shall be construed accordingly.

(10) In this Law "administer", except where the context otherwise requires, 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.

(11) 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 effects which such products when used, or when used in any particular way referred to in the document, advertisement or representation, produce or are intended to produce.

3 Meaning of "wholesale dealing", "retail sale" and related expressions

(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 paragraph (2), except that it does not include any such sale by the person who manufactured it.

(2) The purposes referred to in paragraph (1), 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 or animals,

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 paragraph (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 received 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 or animals,

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

(5) For the purposes of this Article the provision of services by the Minister for Social Security under the Health Insurance (Jersey) Law 1967 shall be treated as the carrying on of a business by that Minister.

PART 2

ADMINISTRATION

4 Minister to administer this Law[3]

(1) Subject to paragraphs (2) and (3), it shall be the duty of the Minister to administer this Law and any Orders made under it.

(2) Where any function (including the making of Orders) falls to be performed in relation to veterinary drugs or the treatment of diseases of

animals, the Minister shall, before performing any such function or making any such Order, consult with the Minister for Economic Development, Tourism, Sport and Culture.[4]

5 Establishment of Medicines Advisory Council

(1) There shall be established a body to be called the Medicines Advisory Council (in this Law referred to as the "Advisory Council") to perform the functions assigned to the Advisory Council under this Law.

(2) The Advisory Council shall consist of–

(a) the Medical Officer of Health;

(b) the Official Analyst;

(c) the States Veterinary Officer;

(d) the Chief Pharmacist; and

(e) not less than 4 other persons, including a doctor and a retail pharmacist, appointed by the Minister after consultation with such organisations as he or she considers appropriate.

(3) The Minister shall appoint one of the members of the Advisory Council to be chairman.

(4) The Advisory Council may appoint sub-Advisory Councils, which may consist in part of persons who are not members of the Advisory Council to consider and report on any matter referred to them by the Advisory Council.

(5) At a meeting of the Advisory Council, the quorum shall be half of the members.

(6) Subject to the foregoing provisions of this Article, the Advisory Council may determine its own procedure.

(7) The Minister may –

(a) pay to the members of the Advisory Council such remuneration as the Minister may determine;

(b) defray such expenses of the Advisory Council as the Minister may determine; and

(c) provide such accommodation and services for the Advisory Council as the Minister thinks fit.

6 General functions of Advisory Council

(1) The Advisory Council shall give to the Minister advice on matters relating to the execution of this Law or the exercise of any power conferred by it, or otherwise relating to medicinal products, where either the Advisory Council consider it expedient, or it is requested by the Minister to do so.

(2) Without prejudice to paragraph (1), and any other duties and powers conferred on the Advisory Council by this Law, it shall be the duty of the Advisory Council –

(a) to advise the Minister on the safety, quality or efficacy of medicinal products generally;

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

(c) to advise the Minister with regard to applications for licences and certificates under this Law;

(d) to perform such other functions as may from time to time be determined by the Minister.

PART 3

LICENCES AND CERTIFICATES RELATING TO MEDICINAL PRODUCTS

7 Licences and certificates[5]

(1) Subject to paragraph (2), the Minister shall be responsible for the grant, renewal, variation, suspension and revocation of licences and certificates for the purposes of this Law.

(2) A valid United Kingdom product licence or a valid marketing authorization shall, subject to paragraphs (4) and (5), have effect for the purposes of this Law as though it were a product licence granted by the Minister for the purposes of Article 8.

(3) Accordingly in Article 8 a reference to a product licence shall be taken to include a reference to a United Kingdom product licence or a marketing authorization.

(4) A United Kingdom product licence or a marketing authorization shall not have effect for the purposes of this Law for a period of one month following the date on which it comes into effect.

(5) The Minister may, after consultation with the Advisory Council, in relation to a United Kingdom product licence or a marketing authorization, prescribe that the licence or authorization shall not have effect for the purposes of this Law.

8 General provisions as to dealing with medicinal products

(1) This Article shall have effect subject to –

(a) any exemptions conferred by or under this Part;

(b) the provisions of this Part relating to clinical trials;

(c) Article 47; and

(d) the provisions of Part 4 and any Order made under that Part.[6]

(2) Except in accordance with a licence granted for the purposes of this Article (in this Law referred to as a "product licence") no person shall, in the course of a business carried on by him or her, and in circumstances to which this paragraph applies –

(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.

(2A) Where a medicinal product is subject to a marketing authorization and it is a condition of the marketing authorization that the product is to be available on one or more of the following bases –

(a) only on prescription;

(b) only from a pharmacy; or

(c) on general sale,

that condition shall have effect, unless an Order made under Part 4 prescribes otherwise, as if any such basis was prescribed by an Order made under Article 57, had effect as a consequence of Article 51 or was prescribed by an Order made under Article 50 as the case may be.[7]

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

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

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

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

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

(6) For the purposes of paragraph (5) a person shall be taken to be responsible for the composition of a medicinal product if (but only if) in the course of a business carried on by him or her –

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

(b) the person manufactures the product otherwise than in pursuance of an order which fulfils the conditions specified in sub-paragraph (a).

(7) In paragraph (5) –

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

(i) vaccines, toxins or serums,

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

(iii) homoeopathic medicinal products, or

(iv) additives for animal feeding stuffs to which Council Directive 70/524/EEC applies;

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

(i) vaccines, toxins or serums,

(ii) veterinary drugs based on radioactive isotopes,

(iii) veterinary drugs specially prepared for administration by a veterinary surgeon or veterinary practitioner to a particular animal or herd which is under the veterinary surgeon's care,

(iv) homoeopathic veterinary drugs, or

(v) additives for animal feeding stuffs to which Council Directive 70/524/EEC applies.

9 Provisions as to manufacture and wholesale dealing

(1) This Article shall have effect without prejudice to the operation of Article 8, but subject to the exemptions and provisions referred to in paragraph (1)(a) to (c) of that Article.

(2) No person shall, in the course of a business carried on by him or her, manufacture or assemble any medicinal product except in accordance with a licence granted for the purposes of this Article (in this Law referred to as a "manufacturer's licence").

(3) No person shall, in the course of a business carried on by him or her –

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

(b) distribute, otherwise than by way of sale, any proprietary medicinal product or ready-made veterinary drug which has been imported,

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

(4) Article 8(7) shall apply for the purposes of paragraph (3) as it applies for the purposes of Article 8(5).

10 Exemptions for doctors, dentists and veterinary surgeons

(1) The restrictions imposed by Articles 8 and 9 do not apply to anything done by a doctor or dentist which –

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

(2) Subject to paragraph (3), the restrictions imposed by Articles 8 and 9 do not apply to anything done by a veterinary surgeon which –

(a) relates to a medicinal product specially prepared for administration to a particular animal or herd which is under the veterinary surgeon's care, and consists of manufacturing or assembling, or procuring the manufacture or assembly of, the product, or of selling or supplying, or procuring the sale or supply of, the product to a person having the possession or control of that animal or herd; or

(b) relates to a medicinal product specially prepared at the request of another veterinary surgeon 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 supply, 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.

(3) Paragraph (2) shall not have effect so as to exempt from the restrictions imposed by Articles 8 and 9 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; 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.

11 Exemptions for pharmacists

(1) Subject to paragraph (2), the restrictions imposed by Articles 8 and 9 do not apply to anything which is done in a registered pharmacy, a hospital or such other place as may be prescribed and is done there by or under the supervision of a pharmacist and consists of –

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

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

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

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

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

(2) The exemption conferred by paragraph (1) 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.

(3) The restrictions imposed by Articles 8 and 9 do not apply to the preparation or dispensing in a registered pharmacy of a medicinal product by or under the supervision of a pharmacist in accordance with a specification furnished by the person to whom the product is or is to be sold or supplied, where –

(a) the product is prepared or dispensed for administration to that person or to a person under the pharmacist's care; or

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

(4) Without prejudice to the foregoing provisions of this Article, the restrictions imposed by Articles 8 and 9 do not apply to anything which is done in a registered pharmacy by or under the supervision of a pharmacist and consists of –

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

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

and those restrictions do not apply to anything which is done in a hospital or such other place as may be prescribed 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 paragraph (1)(a).

(5) Without prejudice to the preceding paragraphs, the restrictions imposed by Article 8 do not apply to the preparation or dispensing in a registered pharmacy of a medicinal product by or under the supervision of a pharmacist where –

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

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

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

(6) Without prejudice to the preceding paragraphs, the restrictions imposed by Article 9(2) do not apply to anything which is done in a registered pharmacy by or under the supervision of a pharmacist and consists of preparing a medicinal product with a view to retail sale or to supply in circumstances corresponding to retail sale at that registered pharmacy.

(7) Without prejudice to the preceding paragraphs, the restrictions imposed by Article 9(3) do not apply to anything which is done in a registered pharmacy by or under the supervision of a pharmacist and amounts to wholesale dealing, where such dealing constitutes no more than an

inconsiderable part of the business carried on by the pharmacist at that pharmacy.

(8) For the purposes of this Article "advertisement" shall have the meaning assigned to it by Article 87, except that it shall not include words inscribed on the medicinal product, or on its container or package.

12 Exemption for nurses and midwives

The restrictions imposed by Article 9 do not apply to the assembly of any medicinal products by a person in the course of that person's profession as a registered nurse or as a certified midwife.

13 Exemptions in respect of herbal remedies

(1) The restrictions imposed by Articles 8 and 9 do not apply to the sale, supply, manufacture or assembly of any herbal remedy in the course of a business where –

(a) the remedy is manufactured or assembled on premises of which the person carrying on the business is the occupier and which he or she 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 or her own judgment as to the treatment required.

(2) The restrictions imposed by Articles 8 and 9 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.

14 Exemptions for imports

(1) The restriction imposed by Article 8(3) does not apply to the importation of a medicinal product by any person for administration to himself, herself or to any person or persons who are members of his or her household, and does not apply to the importation of a medicinal product where it is specially imported by or to the order of a doctor or dentist for administration to a particular patient of his or hers.

(2) Without prejudice to paragraph (1), the restrictions imposed by Article 8(3) shall not apply to the importation of medicinal products in such circumstances as may be prescribed for the purposes of this Article.

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

15 Exemption for re-exports

The restrictions imposed by Articles 8 and 9 do not apply to the exportation, or the sale or offer for sale for the purposes of exportation, of any imported medicinal product if it is, or is to be, exported –

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

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

16 Provision for extending or modifying exemptions

(1) The Minister may by Order provide that Articles 8 and 9 shall have effect subject to such exemptions (other than those for the time being having effect by virtue of Articles 10 to 15) as may be specified in the Order.

(2) Any exemption conferred under paragraph (1) may be subject to such conditions or limitations as may be prescribed.

(3) The Minister may by Order provide that any of the provisions of Articles 10 to 15 of this Law specified in the Order shall cease to have effect, or shall have effect subject to such exceptions or modifications as may be so specified.

17 Transitional exemptions

(1) The restrictions imposed by Articles 8 and 9 do not apply to anything done before the day on which this Article comes into force; and, except as otherwise provided by any Order made under Article 18, the following provisions of this Article shall have effect in relation to things done on or after that day.

(2) Article 8(2) shall not have effect in relation to a person in respect of his or her selling or supplying, or procuring the sale, supply, manufacture or assembly of, medicinal products of any description if, in the course of a business carried on by the person, any medicinal products of that description were sold or supplied, or procured to be sold, supplied, manufactured or assembled, at any time before the day on which this Article comes into force and medicinal products of that description were effectively on the market in Jersey immediately before that day, and either –

(a) information with regard to the composition of medicinal products of that description, and as to their being available for sale or supply in Jersey, 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 Jersey; or

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

(3) Article 8(3) shall not have effect in relation to a person in respect of his or her importing medicinal products of any description in the course of a business carried on by the person if, in the course of that business, medicinal products of that description were imported within the period of 12 months ending with the day on which this Article comes into force.

(4) Article 9(2) shall not have effect in relation to a person in respect of his or her manufacturing or assembling medicinal products of any description in the course of a business carried on by the person if in the course of that business –

(a) medicinal products of that description were manufactured or assembled within the period of 12 months ending with the day on which this Article comes into force; 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,

but this paragraph shall not have effect in relation to any particular operations carried out in the course of a business unless the manufacture or assembly of the products as mentioned in sub-paragraph (a) or (b), as the case may be, included those operations.

(5) Article 9(3) shall not have effect in relation to a person in respect of his or her selling or offering for sale any medicinal products by way of wholesale dealing in the course of a business carried on by the person 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 12 months ending with the day on which this Article comes into force.

18 Termination of transitional exemptions

For the purposes of Article 17(2) to (5), the Minister may by one or more Orders under this Article appoint one or more days, subsequent to the day on which Article 17 comes into force, and may by any such Order provide that such one or more of those paragraphs 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 any class of medicinal products.

19 Application for licence

(1) Any application for the grant of a licence under this Part shall be made to the Minister in such form and manner, and shall contain, or be

accompanied by, such information, documents, samples and other material, as the Minister may prescribe.

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

(3) An application for a product licence shall not be made in respect of medicinal products in respect of which there is in existence a United Kingdom product licence or a marketing authorization unless the Minister has prescribed, under Article 7(5), that the product licence or authorization shall be of no effect for the purposes of this Law.[8]

20 Factors relevant to determination of application for licence

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

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

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

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

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

(3) Nothing in paragraph (2) shall be construed as requiring the Minister, in considering the safety of medicinal products of a particular description, in relation to a purpose for which they are proposed to be administered, to leave out of account any question whether medicinal products of another description, being equally or more efficacious for that purpose, would or might be safer in relation to that purpose.

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

(a) an undertaking, given by the manufacturer of any such products, to permit the premises where they are or are to be manufactured, and

the operations carried on or to be carried on in the course of manufacturing them, to be inspected by or on behalf of the Minister;

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

(c) a declaration, given by or on behalf of the manufacturer of any such products, that, in relation to the manufacture or 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.

(5) Where any such application indicates that the purposes for which the licence is required relate exclusively to the exportation of medicinal products, the Minister shall leave out of account considerations of safety and efficacy if satisfied that in the circumstances it is reasonable to do so.

(6) In dealing with an application for a manufacturer's licence the Minister shall in particular take into consideration –

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

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

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

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

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

(7) In dealing with an application for a wholesale dealer's licence the Minister 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 the safekeeping of, and the maintenance of adequate records in respect of, medicinal products stored on or distributed from those premises.

21 Grant or refusal of licence

(1) Subject to Article 20, and to the following provisions of this Law, on any application for a licence under this Part of this Law the Minister –

(a) may grant a licence containing such provisions as the Minister considers appropriate; or

(b) if, having regard to the provisions of this Law, he or she considers it necessary or expedient to do so, may refuse to grant a licence; or

(c) may grant a licence otherwise than in accordance with the application.

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

(3) The Minister shall not refuse to grant a licence under this Part except after consultation with the Advisory Council.

22 Procedure on refusal of application[9]

Where, in pursuance of this Part the Minister proposes –

(a) to refuse to grant a licence; or

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

the Minister shall within 28 days of receipt of the application notify the applicant accordingly and, before determining the application, shall afford the applicant an opportunity of appearing before and being heard by, or of making representations in writing to, the Minister.

23 Appeal to Royal Court

Where, in pursuance of this Part the Minister, after having considered –

(a) any representations made by the applicant; and

(b) the recommendations of the Advisory Council,

refuses to grant a licence or proposes to grant a licence otherwise than in accordance with the application, the Minister shall forthwith inform the applicant of the Minister's decision and the reason for it, and the applicant may, within one month of receipt of the notice, appeal to the Royal Court, either in term or vacation against the decision on the grounds that, having regard to all the circumstances of the case, the decision was unreasonable.

24 Special provisions as to effect of manufacturer's licence

(1) Subject to the provisions of this Part relating to clinical trials and to the following provisions of this Article a manufacturer's licence shall not have effect so as to authorize the manufacture or assembly of medicinal products of any description for sale or supply to any other person, or for exportation, unless either –

(a) the holder of the licence is also the holder of a product licence or a United Kingdom product licence or marketing authorization which has effect for the purposes of this Law which is applicable to medicinal products of that description; or

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

and (in either case) the products are manufactured or assembled in accordance with that product licence or authorization.[10]

(2) Subject to paragraph (3), the foregoing provisions of this Article 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 hers or is required, at the request of another doctor or dentist, for administration to a patient of that other doctor or dentist; or

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

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

(3) The exemption conferred by paragraph (2) –

(a) in a case falling within paragraph (2)(b);

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

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

(4) If, by virtue of an Order made under Article 16 an exemption is conferred in respect of the restrictions imposed by Article 8, but no corresponding exemption is conferred in respect of the restrictions imposed by Article 9(2), the Order may provide that paragraph (1) shall have effect subject to such exceptions or modifications as the Minister considers appropriate in the circumstances.

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

25 Duration and renewal of licence

(1) Subject to the following provisions of this Article, every licence granted under this Part, unless previously renewed or revoked, shall expire at the end of the period of 5 years from the date on which it was granted or the date as from which it was last renewed, as the case may be, or at the end of such shorter period from that date as may be specified in the licence as granted or last renewed.

(2) Where any licence has been granted under this Part and the Minister subsequently considers that it would no longer be possible to grant that licence without contravening any EU obligation which binds Jersey, the licence shall (notwithstanding paragraph (1)) expire on such date as may be specified in a notice served on the holder of the licence by the Minister.[11]

(3) Any such licence, if it has not been revoked, may, on the application of the holder of the licence, be renewed by the Minister for a further period of 5 years from the date on which it would otherwise expire or such shorter period from that date as the Minister may determine.

(4) On an application for the renewal of a licence under this Part, the Minister may –

(a) renew the licence, with or without modifications, for such a further period as is mentioned in paragraph (3);

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

(c) if, having regard to the provisions of this Law, the Minister considers it necessary or expedient to do so, refuse to renew the licence or to grant a new licence.

(5) In relation to any such application, Articles 19, 20, 21(2) and (3), 22 and 23 shall have effect as if in those provisions any reference to refusing a licence included a reference to refusing to renew a licence and any reference to granting a licence included a reference to renewing it.

(6) Subject to paragraph (7), a United Kingdom product licence or a marketing authorization which has effect for the purposes of this Law shall continue in effect for those purposes for so long as it remains in effect in the United Kingdom.[12]

(7) Except as provided by paragraph (8), if a United Kingdom product licence or a marketing authorization which has effect for the purposes of this Law is modified on renewal it shall continue to have effect for those purposes.[13]

(8) The Minister may, after consultation with the Advisory Council, determine that the licence or authorization as so modified shall no longer have effect for the purposes of this Law.[14]

26 Licences of right

(1) Where any of the provisions of Article 17(2) to (5) has effect in relation to a person, he or she may make an application in accordance with Article 19, stating that it is an application for a licence of right.

(2) On an application made in pursuance of paragraph (1) the applicant, on proving that any of the provisions of Article 17(2) to (5) has effect in relation to the person, shall be entitled to the grant of a licence under this Part in accordance with the provisions of Article 27.

(3) In this Article and in Articles 27 and 28 any reference to proof is a reference to proof to the reasonable satisfaction of the Minister.

(4) In this Law "licence of right" means –

(a) a licence to which a person is entitled by virtue of this Article, including such a licence which has been renewed (with or without modifications) but not a licence granted instead of the renewal of such a licence; or

(b) a licence of right issued by virtue of section 25(1) of the Medicines Act.

27 Scope of licence of right in different cases

(1) Where a person is entitled to the grant of a licence of right by reason that Article 17(2) or (3) has effect in relation to him or her, he or she shall be entitled to the grant of a product licence, but, subject to the following provisions of this Article –

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

(b) where the conditions specified in paragraph (3) (but not those specified in paragraph (2)) of that Article are proved to have been fulfilled, then, without prejudice to paragraph (1) of this Article, the licence granted shall be limited to the importation of medicinal products.

(2) Where a person is entitled to the grant of a licence of right by reason that Article 17(4) has effect in relation to him or her, he or she shall be entitled to the grant of a manufacturer's licence; but, subject to the following provisions of this Article, the licence shall be granted so as not to extend –

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

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

(3) Where a person is entitled to the grant of a licence of right by reason that Article 17(5) has effect in relation to him or her, he or she shall be entitled to the grant of a wholesale dealer's licence.

(4) A licence of right granted in accordance with paragraph (1) or (2) shall be granted subject to such conditions as appear to the Minister to be requisite for securing that the specification of medicinal products of any description to which the licence relates, and the purposes for which any such products are authorized by the licence to be sold, supplied, exported, imported, manufactured or assembled, will be in accordance with those stated in the application for the licence.

(5) Where a licence of right is granted under this Article in circumstances where, immediately before the day on which Article 17 comes into force, the manufacture or importation of medicinal products of any description

to which the licence relates was authorized by a licence issued under Part 3 of the Diseases of Animals (Jersey) Law 1956, the provisions of the licence so issued shall be deemed to be incorporated in the licence of right in its application to medicinal products of that description and shall have effect accordingly until it expires or is renewed.

28 Procedure on refusal of application for licence of right

Articles 21(3), 22 and 23 shall have effect in relation to an application for a licence of right in any case where the Minister proposes –

(a) to refuse to grant a licence on the grounds that none of the provisions of Article 17(2) to (5) has been proved to have effect in relation to the applicant; or

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

29 General power to suspend, revoke or vary licences

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

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

(3) The powers conferred by this Article shall not be exercisable in relation to a product licence issued under this Part except on one or more of the following grounds, that is to say –

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

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

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

(d) that the holder of the licence has without reasonable excuse failed to comply with a requirement imposed on the holder of the licence under Article 43(2) to furnish information to the Minister with respect to medicinal products or any such description;

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

(f) in the case of a licence other than a licence of right, that the holder of the licence has not, within 2 years after the grant of the licence,

notified to the Minister, 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 Jersey;

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

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

(i) that any of the provisions of the licence, insofar as they relate to the incorporation in animal feeding stuffs of any medicinal product are not in accordance with any EU obligation which binds Jersey;

(j) that, in relation to medicinal products of any description to which the licence relates any of the provisions contained in Orders which –

(i) are made under Article 82; and

(ii) impose requirements which give effect to any EU obligation which binds Jersey,

has to a material extent been contravened by the holder of the licence or by a person procured by the holder of the licence to manufacture or assemble such medicinal products.[15]

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

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

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

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

(d) that the holder of the licence has without reasonable excuse failed to comply with a requirement imposed on the holder of the licence under Article 43(2) with respect to medicinal products of a description to which the licence relates.

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

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

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

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

(7) Articles 21(3), 22 and 23 shall have effect where the Minister proposes to suspend, vary or revoke a licence in pursuance of this Article.

30 Procedure for suspension of licence in case of urgency

(1) Notwithstanding the foregoing provisions of this Part, the Minister may, where it appears that it is necessary to do so in the interests of safety, suspend a licence with immediate effect for a period not exceeding 3 months.

(2) Where the Minister suspends a licence in pursuance of paragraph (1), the Minister shall forthwith notify the holder of the licence and the Advisory Council.

(3) Where, on the expiration of the 3 months referred to in paragraph (1) it appears to the Minister that it is not in the interests of safety to lift the suspension, the Minister may either –

(a) renew the suspension for further periods not exceeding 3 months; or

(b) on giving notice to the holder of the licence of the Minister's proposal so to do, revoke or vary the licence.

(4) Articles 21(3), 22 and 23 shall have effect in relation to a proposal to revoke or vary a licence in pursuance of this Article.

31 Variation of licence on application of holder[16]

Without prejudice to any power exercisable by virtue of Article 29 the Minister may, on the application of the holder of a licence under this Part, vary the provisions of the licence in accordance with any proposals contained in the application, if the Minister is satisfied that the variation will not adversely affect the safety, quality or efficacy of medicinal products of any description to which the licence relates.

32 Clinical trials

(1) In this Law "clinical trial" means an investigation or series of investigations consisting of the administration of one or more medicinal products of a particular description –

(a) by, or under the direction of, a doctor or dentist to one or more patients of the doctor's or dentist's; or

(b) by, or under the direction of, 2 or more doctors or dentists, each product being administered by, or under the direction of, one or other of those doctors or dentists to one or more patients of his or hers,

where (in any such case) there is evidence that medicinal products of that description have effects which may be beneficial to the patient in question and the administration of the product or products is for the purpose of ascertaining whether, or to what extent, the product has, or the products have, those or any other effects, whether beneficial or harmful.

(2) Subject to the following provisions of this Part, no person shall, in the course of a business carried on by him or her –

(a) sell or supply any medicinal product for the purposes of a clinical trial;

(b) procure the sale or supply of any medicinal product for the purposes of a clinical trial; or

(c) procure the manufacture or assembly of any medicinal product for sale or supply for the purposes of a clinical trial,

unless one or other of the conditions specified in paragraph (3) is fulfilled.

(3) The conditions referred to in paragraph (2) are –

(a) that the person is the holder of a product licence which authorizes the clinical trial in question, or does it to the order of the holder of such a licence, and (in either case) the person does it in accordance with that licence;

(b) that a certificate for the purposes of this Article (in this Law referred to as a "clinical trial certificate") has been issued certifying that, subject to the provisions of the certificate, the Minister has consented to the clinical trial in question and that certificate is for the time being in force and the trial is to be carried out in accordance with that certificate.

(4) Subject to the following provisions of this Article, no person shall import any medicinal product for the purposes of a clinical trial unless either –

(a) he or she is the holder of a product licence which authorizes that clinical trial or imports the product to the order of the holder of such a licence, and (in either case) he or she imports it in accordance with that licence; or

(b) a clinical trial certificate has been issued as mentioned in paragraph (3)(b) and that certificate is in force and the trial is to be carried out in accordance with that certificate.

(5) Subject to paragraph (6), the restrictions imposed by the foregoing provisions of this Article do not apply to a doctor or dentist in respect of his or her selling or supplying, or procuring the sale or supply of, a medicinal product, or procuring the manufacture or assembly of a medicinal product specially prepared to his or her order, or specially

importing a medicinal product, where (in any such case) the doctor or dentist is, or acts at the request of, the doctor or dentist by whom, or under whose direction, the product is to be administered.

(6) The exemptions conferred by paragraph (5) do not apply in a case where the clinical trial in question is to be carried out under arrangements made by, or at the request of, a third party (that is to say, a person who is not the doctor or dentist, or one of the doctors or dentists, by whom, or under whose direction, one or more medicinal products are to be administered in that trial).

(7) The restrictions imposed by paragraph (2) do not apply to anything which is done in a registered pharmacy, a hospital or such other place as may be prescribed and is done there by or under the supervision of a pharmacist in accordance with a prescription given by a doctor or dentist; 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 doctor or dentist, or of procuring the assembly of a medicinal product.

(8) The restrictions imposed by paragraph (2) also do not apply to anything done in relation to a medicinal product where –

(a) it is done by the person who, in the course of a business carried on by him or her, has manufactured or assembled the product, where he or she has manufactured or assembled it to the order of a doctor or dentist who has stated that it is required for administration to a patient of his or hers or is required, at the request of another doctor or dentist, for administration to a patient of that other doctor or dentist;

(b) it is done by the person who, in the course of a business carried on by him or her, 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 sub-paragraph (a) or (b).

(9) For the purposes of this Article a product licence shall be taken to be a licence which authorizes a particular clinical trial if –

(a) the trial is to be a trial of medicinal products of a description to which the licence relates; and

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

(10) A clinical trial certificate may certify as mentioned in paragraph (3)(b) without specifying the doctor or dentist (or, if there is to be more than one, any of the doctors or dentists) by whom any medicinal product is to be administered, or the patient or patients to whom any medicinal product is to be administered.

33 Prohibition of medicinal tests on animals

(1) Subject to Article 34, no person shall, in the course of a business carried on by him or her –

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

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

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

(2) No person shall import any medicinal product for the purposes of a medicinal test on animals.

(3) No person shall, in the course of a business carried on by him or her, 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 the administration is covered by a licence granted under a scheme established by Regulations made under Article 11(2) of the Animal Welfare (Jersey) Law 2004.[17]

(4) 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 medicinal product of a particular description to one or more animals, where there is evidence that 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 medicinal product to one or more animals in circumstances where there is no such evidence as is mentioned in sub-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 medicinal product, to one or more animals for the purpose of ascertaining whether it has any effects relevant to a medicinal purpose, whether there is evidence that it has effects which may be beneficial to, or otherwise advantageous in relation to, that animal or those animals, or not.

34 Exemptions in respect of prohibition of medicinal tests on animals

(1) Subject to paragraph (3), the restrictions imposed by Article 33(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 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 medicinal product in

accordance with a prescription given by a veterinary surgeon or of procuring the assembly of a medicinal product.

(2) Subject to paragraph (3), the prohibitions imposed by Article 33(1) do not apply to anything done in relation to a medicinal product where –

(a) it is done by the person who, in the course of a business carried on by him or her, 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 or her 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 or her, 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 sub-paragraph (a) or (b).

(3) The exemptions conferred by paragraphs (1) and (2) 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.

35 Restriction as to animals on which medicinal tests have been carried out

(1) No person shall in the course of a business carried on by him or her sell or supply for human consumption an animal to which in the course of that business a substance or article has been administered by way of a test to which this Article applies, or the carcase or any part of the carcase or any produce of such an animal.

(2) This Article 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 or her 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.

36 Supplementary provisions as to clinical trials

(1) The restrictions imposed by Article 8 do not apply to anything done in accordance with a clinical trial certificate.

(2) The restrictions imposed by Article 9(2) do not apply to the manufacture or assembly of any medicinal product for the sole purpose of its being administered by way of a clinical trial, or of its being sold, supplied or exported for the sole purpose of being so administered.

(3) Neither the restrictions imposed by Article 8 nor those imposed by Article 32(2) apply to anything done exclusively for the purpose of a clinical trial which is to be carried out wholly outside Jersey.

(4) Where the holder of a manufacturer's licence manufactures or assembles any medicinal product for sale or supply for the purposes of a clinical trial and –

(a) a clinical trial certificate has been issued and is in force in respect of that trial, and the trial 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 trial,

then, if the conditions specified in Article 24(1) are not fulfilled in relation to the products, that Article shall have effect in relation to it as if those conditions were fulfilled.

(5) For the purposes of Article 32 a person shall not be treated as doing anything, or procuring anything to be done, for the purposes of a clinical trial if –

(a) the trial is, or is to be, carried out under arrangements to which the person is not a party; and

(b) the person has not been informed of those arrangements.

(6) The Minister may by Order provide that Article 32(2) or (4) shall have effect subject to such exemptions (other than those for the time being having effect by virtue of paragraphs (5) to (8) of that Article and paragraph (3) as may be specified in the Order.

(7) Any exemption conferred by an Order under paragraph (6) may be conferred subject to such conditions or limitations as may be specified in the Order.

(8) The Minister may by Order provide that any of the provisions of Article 32(5) to (8), or any of the provisions of Article 34, or paragraph (3), shall cease to have effect, or shall have effect subject to such exceptions or modifications as may be specified in the Order.

37 Application for, and issue of, certificate

(1) Any application for a clinical trial certificate shall be made to the Minister and shall be made in such form and manner, and shall contain, or be accompanied by, such information, documents, samples and other material, as may be prescribed.

(2) In dealing with any such application, the Minister shall have regard in particular to any evidence available to the Minister as to any risks involved in the proposed clinical trial.

(3) Subject to Article 38, Articles 21 to 23 shall have effect in relation to applications for clinical trial certificates, as if in those Articles any reference to a licence under this Part were a reference to such a certificate.

38 Transitional provisions as to clinical trials

(1) Articles 32 and 37 shall have effect subject to the following provisions of this Article.

(2) The restriction imposed by Article 32 does not apply to anything done before the day on which Article 17 comes into force.

(3) Where, in the course of a series of investigations carried out during a period ending on the day on which Article 17 comes into force, medicinal products of a particular description have been administered by way of a clinical trial, the restrictions imposed by Article 32 do not apply to anything done in relation to medicinal products of that description or for the purpose of continuing that series of investigations, if it is done on or after the day on which Article 17 comes into force but before such date as may be appointed for the purposes of this Article by an Order made by the Minister.

(4) If, on an application for a clinical trial certificate which is made before the date appointed for the purposes of this Article, it is proved to the reasonable satisfaction of the Minister that –

(a) medicinal products of a description specified in the application were administered by way of a clinical trial in the course of a series of investigations as mentioned in paragraph (3);

(b) that series of investigations was in progress immediately before the day on which Article 17 comes into force; and

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

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

(5) Article 37(3) shall not have effect in relation to an application for a certificate as being a certificate to which the applicant is entitled by virtue of Article 28(4) shall have effect in relation to any such application, as if –

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

(b) for the reference in sub-paragraph (a) of that Article to the grounds of refusal therein mentioned there were substituted a reference to the grounds that the conditions specified in paragraph (4) have not been fulfilled in relation to the application,

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

39 Duration and renewal of certificate

(1) Subject to this Article, every clinical trial certificate, unless previously renewed or revoked, shall expire at the end of the period of 2 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 Minister for a further period of 2 years from the date on which it would otherwise expire or such shorter period from that date as the Minister may determine.

(3) Article 37(1) and (2) 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 certificate.

(4) On an application for the renewal of such a certificate the Minister may –

(a) renew the certificate, with or without modifications, for such a further period as is mentioned in paragraph (2);

(b) issue to the applicant a new clinical trial certificate containing such provisions as the Minister considers appropriate; or

(c) if, having regard to the provisions of this Law the Minister considers it necessary or expedient to do so, refuse to renew the certificate or to issue a new certificate.

(5) In relation to any such application Articles 21(2) and (3), 22 and 23 shall have effect as if in those provisions any reference to refusing a licence under that Part included a reference to refusing to renew a clinical trial 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 a clinical trial certificate shall, unless it expressly provides otherwise, be taken to be an application for the grant or renewal of the certificate for the full period of 2 years mentioned in paragraph (1) or (2), as the case may be; and, in any provisions of Article 22 or 23 as applied by paragraph (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 the certificate shall not cease to be in force by virtue of the foregoing provisions of this Article before the Minister has determined the application.

40 Suspension, revocation or variation of certificate

(1) Subject to the following provisions of this Article the Minister may suspend, for such period as he or she may determine, a clinical trial certificate, or may revoke, or vary the provisions of, any such certificate.

(2) The powers conferred by this Article shall not be exercisable except on one or more of the following grounds, that is to say –

(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 being contravened;

(c) that medicinal products of any description to which the certificate relates, as sold, supplied, exported, imported, manufactured or assembled for the purposes of the clinical trial 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 the holder of the certificate under Article 43 to furnish information to the Minister 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 clinical trial to which the certificate relates;

(f) that the specification and standards to which any such substances or articles are manufactured can no longer be regarded as satisfactory.

(3) Article 30 shall have effect in relation to a clinical trial certificate as it has effect in relation to a product licence.

(4) Without prejudice to any power exercisable by virtue of the foregoing provisions of this Article, the Minister may, on the application of the holder of a clinical trial certificate, vary the provisions of the certificate in accordance with any proposals contained in the application, if the Minister is satisfied that the variation will not adversely affect the safety, quality or efficacy of medicinal products of any description to which the certificate relates.

41 Medicated animal feeding stuffs

(1) The Minister may by Order prohibit the incorporation by any person, in the course of a business carried on by him or her, of a medicinal product of any description in an animal feeding stuff unless such of the conditions mentioned in paragraph (2) as may be specified in the Order are satisfied.

(2) The conditions referred to in paragraph (1) are –

(a) that it is incorporated in accordance with provisions relating to the incorporation of the medicinal product in animal feeding stuffs contained in a product licence or a United Kingdom product

licence or marketing authorization which has effect for the purposes of this Law (whether held by him or her 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 Order.[18]

(3) A condition imposed by virtue of paragraph (2)(a) shall be taken to be satisfied if the person incorporating the medicinal product in the animal feeding stuff –

(a) is not the holder of a product licence or a United Kingdom product licence or marketing authorization which has effect for the purposes of this Law containing such provisions as are mentioned in that paragraph; but

(b) believes, on reasonable grounds, that another person is the holder of such a licence or authorization containing such provisions and that the medicinal product is incorporated in accordance with those provisions.[19]

(4) The Minister may by Order prohibit –

(a) the sale, offer for sale, supply or export by any person in the course of a business carried on by him or her of any animal feeding stuff in which a medicinal product has been incorporated; or

(b) the importation by any person of any animal feeding stuff in which a medicinal product has been incorporated,

unless such of the conditions mentioned in paragraph (5) as may be specified in the Order are satisfied.

(5) The conditions referred to in paragraph (4) are –

(a) that the medicinal product was not incorporated in the animal feeding stuff in contravention of any prohibition imposed by virtue of paragraph (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 Order.

(6) A condition imposed by virtue of paragraph (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 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 paragraph (1).

(7) A person contravenes this Article if he or she contravenes any prohibition imposed by virtue of paragraph (1) or (4).

(8) References in this Law to the incorporation of a medicinal product in an animal feeding stuff do not include a reference to it being so incorporated

in the course of making a 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 medicinal product; or

(b) of a substance in which a medicinal product has been incorporated,

in an animal feeding stuff.

42 Extension of Article 8 to certain special circumstances

(1) Subject to paragraph (2), where in the course of a business carried on by the person he or she sells, supplies or exports a substance or article for use wholly or mainly in either or both of the ways specified in Article 2(1) 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, Article 8(2), if apart from this paragraph it would not so have effect, shall have effect in relation to the sale, supply or exportation of the substance or article as if the person were selling, supplying or exporting it in circumstances to which that paragraph applies.

(2) Paragraph (1) shall not have effect in relation to a transaction whereby a person, in the course of a business carried on by him or her, 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 the person.

(3) In any reference in this Part to the provisions of, or the restrictions imposed by Article 8, the reference to that Article shall be construed as including a reference to paragraph (2) of that Article as extended by paragraphs (1) and (2).

(4) Where in the course of a business carried on by him or her a person proposes to sell, supply or export a substance or article for use as mentioned in paragraph (1), where the substance or article will not constitute a medicinal product before he or she so sells, supplies or exports it and he or she will not be selling, supplying or exporting it in circumstances to which Article 8(2) applies, the person may, if he or she so desires, and if he or she does not hold a United Kingdom product licence or a marketing authorization which has effect for the purposes of this Law in respect of that substance or article, apply for a product licence in respect of that substance or article, and the Minister, subject to Articles 20 to 23, may grant to the person a product licence in respect of it, as if he or she were proposing to sell, supply or export it in circumstances to which Article 8(2) applies; and a product licence so granted may be renewed, suspended, revoked or varied accordingly.[20]

(5) In paragraph (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 Article 1(1)) would constitute assembling if it had been a medicinal product when sold or supplied to the person.

43 Provision of information to Minister

(1) Where an application has been made for a licence under this Part (including a licence of right) or for a clinical trial certificate (including a certificate to which a person is entitled by virtue of Article 38(4)) the Minister, before determining the application, may request the applicant to furnish such information relating to the application as the Minister may consider requisite; and, where any such request has been made, the Minister shall not be required to determine the application until either –

(a) the information requested has been furnished to the Minister; or

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

(2) The Minister may serve on the holder of a licence under this Part, or of a clinical trial certificate, a notice requiring the holder of the licence, within such time as may be specified in the notice, to furnish information of any description specified in the notice in accordance with the following provisions of this Article.

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

(4) Paragraph (3) shall not have effect in the case of a licence of right, or of a certificate issued in pursuance of Article 38(4) whether the licence or certificate has been renewed or not; and, in the case of such a licence or certificate, a notice under this Article may be served at any time and may require any information which, in the opinion of the Minister, would be relevant if –

(a) Articles 26 and 38(4) had not been enacted; and

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

(5) Before the end of the period of 2 years from the date on which a product licence, other than a licence of right, is granted, the holder of the licence shall, in respect of each description of medicinal products to which the licence relates which is effectively on the market in Jersey within that period, notify to the Minister a date on which medicinal products of that description were effectively on that market.

44 Offences under Part 3[21]

(1) Subject to Article 45, a person who contravenes a provision of Article 8, 9, 32, 33, 35 or 41 or who is in possession of a medicinal product or animal feeding stuff for the purpose of selling, supplying or exporting it in contravention of any of those Articles, shall be guilty of an offence.

(2) If a medicinal product or animal feeding stuff is imported in contravention of Article 8, 32, 33 or 41, a 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) A person who, being the holder of a product licence, or of a United Kingdom product licence or a marketing authorization which has effect for the purposes of this Law, or of a clinical trial certificate, procures another person to carry out a process in the manufacture or assembly of medicinal products of a description to which the licence, authorization or certificate relates, and –

(a) does not communicate to that person the provisions of the licence, authorization 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 Minister, or in the case of a United Kingdom product licence or marketing authorization by the licensing authority, does not communicate the variation to that person within 14 days after the notice of the decision has been served on the holder,

shall be guilty of an offence.

(4) A person who, being the holder of a product licence, or a United Kingdom product licence or a marketing authorization which has effect for the purposes of this Law, sells or supplies a substance or article to which the licence or authorization relates to another person for the purpose of its being incorporated in animal feeding stuff, and does not communicate to that person any provisions of the licence, authorization or certificate which relate to the incorporation of that substance or article in animal feeding stuffs, or any instructions required by the licence or authorization to be communicated by the holder to persons to whom the substance or article is sold or supplied for that purpose, shall be guilty of an offence.

(5) Where any such provisions of a product licence, or a United Kingdom product licence or marketing authorization which has effect for the purposes of this Law as are mentioned in paragraph (4) are varied by the Minister or, as the case may be, the licensing authority, and on varying those provisions the Minister or the licensing authority serves on the holder of the licence or authorization a notice requiring the holder, within such time (not being less than 14 days from the date of service of the notice) as may be specified in the notice, to take such steps as may be 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 authorization does not comply with the requirements of that notice the holder shall be guilty of an offence.

(6) A person who, in giving information which he or she is required to give under Article 43, makes a statement which he or she knows to be false in a material particular shall be guilty of an offence.

(7) A person who without reasonable excuse fails to comply with a requirement imposed on him or her by a notice under Article 43(2) shall be guilty of an offence.

(8) A person guilty of an offence under any of paragraphs (1) to (6) shall be liable to imprisonment for a term not exceeding 2 years or to a fine or to both.

(9) A person guilty of an offence under paragraph (7) shall be liable to a fine not exceeding level 2 on the standard scale.

(10) In this Article "the licensing authority" –

(a) in relation to a United Kingdom product licence, has the same meaning as in section 6 of the Medicines Act of the United Kingdom;

(b) in relation to a marketing authorization that is a marketing authorisation as defined by the Veterinary Medicines Products Regulations 1994 of the United Kingdom, means the Ministers as defined in those Regulations or any one of those Ministers acting alone or any 2 or more of them acting jointly;

(c) in relation to a marketing authorization which is a Community marketing authorization as defined by the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 of the United Kingdom, means the European Commission; and

(d) in relation to a marketing authorization which is a United Kingdom marketing authorization as defined by the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 of the United Kingdom, means the licensing authority under those Regulations.

45 Special defences under Article 44

(1) Where the holder of a product licence, a United Kingdom product licence or marketing authorization which has effect for the purposes of this Law or a clinical trial certificate is charged with an offence under Article 44 in respect of any substance or article which has been manufactured (or, in the case of a medicinal product, manufactured or assembled) to the licence holder's order by another person and has been so manufactured or assembled as not to comply with the provisions of that licence, authorization or certificate which are applicable to it, it shall be a defence for the holder of the licence to prove –

(a) that the holder of the licence had communicated those provisions to that other person; and

(b) that the holder of the licence did not know, and could not by the exercise of reasonable care have discovered, that those provisions had not been complied with.[22]

(2) Where the holder of a manufacturer's licence is charged with an offence under Article 44 in respect of any medicinal products which have been manufactured or assembled by the holder of the licence, in circumstances where he or she is not the holder of a product licence or of a clinical trial 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 or her to prove that the holder of the licence believed, and had reasonable grounds for believing –

(a) that the other person in question was the holder of a product licence applicable to those products, or of a clinical trial certificate applicable to them; and

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

46 Standard provisions for licences or certificates

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

(2) Any standard provisions so prescribed may be incorporated in any licence under this Part or any clinical trial certificate granted or issued on or after the date on which the Order comes 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) This Article shall have effect where –

(a) standard provisions are prescribed under this Article; or

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

and in this Article, in a case falling within sub-paragraph (a), the "operative standard provisions" means the standard provisions prescribed by the Order and, in any other case, the "operative standard provisions" means the standard provisions as amended by the subsequent Order or the new standard provisions prescribed by that Order, as the case may be.

(4) Subject to the following provisions of this Article as from the end of the period of 3 months from the date on which an Order made under this Article comes into operation, the operative standard provisions shall be deemed to be incorporated in any licence under this Part, or any clinical trial certificate which is in force at the end of that period or, in the case of a suspended licence or certificate, would then be in force if it were not suspended, insofar as, in accordance with the relevant Order, the operative standard provisions are applicable to medicinal products of any description to which that licence or certificate relates.

(5) Notwithstanding paragraph (4), the operative standard provisions shall not, by virtue of that paragraph be deemed to be incorporated in any

licence of right, or in any certificate issued in pursuance of Article 38(4), including any such licence or certificate which has been renewed, except in circumstances where, immediately before the day on which Article 17 comes into force, the manufacture or importation of substances or articles to which the licence or certificate relates was authorized by a licence issued under Part 3 of the Diseases of Animals (Jersey) Law 1956 and, where those circumstances exist, shall be deemed to be so incorporated only in relation to substances or articles to which the licence so issued was applicable.

(6) At any time after the relevant Order is made and before the end of the period of 3 months from the date on which it comes into force, the holder of any licence or certificate, may apply to the Minister to direct that –

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

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

and if the Minister directs that the operative standard provisions shall not be deemed to be so incorporated, or shall be deemed to be so incorporated subject to exceptions and modifications specified in the direction, with or without provision postponing the date as from which they are to be deemed to be so incorporated, that direction shall have effect notwithstanding anything in paragraph (4).

(7) Where an application is made under paragraph (6), then, if the Minister proposes to refuse to give a direction in accordance with the application –

(a) the Minister shall, before determining the application, afford the applicant an opportunity of appearing before, and being heard by, or making written representations to, the Minister with respect to that proposal; and

(b) if the Minister then determines to refuse to give a direction in accordance with the application, he or she shall serve on the applicant a notice stating the reasons for the Minister's decisions.

(8) Without prejudice to any direction given under paragraph (6), where such an application is made the operative standard provisions shall not be deemed to be incorporated in the licence or certificate to which the application relates before the Minister has made a decision on that application.

(9) The powers conferred on the Minister by this Article to vary the provisions of a licence or certificate shall be exercisable with respect to any provisions which, in accordance with this Article, are incorporated or deemed to be incorporated in a licence or certificate.

47 Postponement of restrictions in relation to exports

(1) Notwithstanding Articles 8 to 46, but subject to Article 48, in relation to anything done before such day (subsequent to the day on which Article 17 comes into force) as the Minister may by Order appoint for the

purposes of this Article (in this Article referred to as the "special appointed day"), those Articles 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 purpose 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 Minister shall not make an Order under paragraph (1) unless it appears to the Minister to be necessary or expedient to do so for the purpose of giving effect to any EU obligation which binds the Island or will bind the Island on the day appointed by the Order.[23]

(3) The following provisions of this Article shall have effect where an Order is made under paragraph (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 the person –

(a) substantial quantities of medicinal products of that description (that is to say, quantities exceeding those required for distribution as samples) were exported or procured to be exported during the period of 24 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 paragraph –

(a) subject to any Order made by virtue of sub-paragraph (b) of this paragraph, Article 8(2) shall not have effect in relation to a person in respect of his or her 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 or she fulfils the relevant transitional conditions;

(b) Article 18 shall have effect in relation to sub-paragraph (a) of this paragraph as it has effect in relation to the sub-paragraphs of Article 17 mentioned in that Article.

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

(a) it also authorized the holder of the licence 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 authorized the holder of the licence 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.

(6) If the operation of paragraph (4) is not excluded by the Order, a product licence shall not have effect as mentioned in this Article in relation to medicinal products of any description so long as paragraph (4)(a) has effect in relation to the holder of the licence in respect of the licence holder's exporting, or procuring the exportation of, medicinal products of that description.

(7) Where on an application for a product licence made before such date as may be appointed by Order for the purposes of this paragraph, which states that it is an application made by virtue of this paragraph, it is proved to the reasonable satisfaction of the Minister that the applicant fulfilled or will fulfil the relevant transitional conditions in relation to one or more descriptions of medicinal products, then, subject to paragraph (8), the applicant shall be entitled to the grant of a product licence granted so as –

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

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

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

(8) If a person would, on making an application under paragraph (7), be entitled to the grant of a product licence under that paragraph in respect of medicinal products of a particular description, and the person would at the same time, on making an application as mentioned in Article 26(1) be entitled to the grant of a licence of right in respect of medicinal products of the same description, he or she may apply to the Minister for a single product licence for both purposes, and shall be entitled to the grant of a product licence having the same effect as the 2 licences, if granted separately, would together have had.

(9) An Order made under paragraph (1) may contain such provisions relating to proceedings on an application made under paragraph (7) or (8) as the Minister considers appropriate.

48 Special provision in respect of exporting certain products

(1) Nothing in Article 47(1) shall affect the operation of any of the provisions of Articles 8 to 46 in relation to any medicinal product falling within a class specified in an Order made under this Article by the Minister.

(2) No class of medicinal products shall be specified in an Order made under this Article unless it appears to the Minister to be requisite for securing that any exemption conferred by Article 47(1) does not apply to

medicinal products consisting wholly or partly of substances the purity or potency of which cannot, in the Minister's opinion, be adequately tested by chemical means.

(3) Article 47(3) to (8) shall not have effect in relation to medicinal products of any description falling within a class specified in an Order under this Law which is in force immediately before the day appointed for the purpose of paragraph (1) of that Article.

(4) Subject to paragraph (5), Article 8(2) shall not have effect in relation to a person in respect of his or her exporting, or procuring the exportation of, medicinal products of any description falling within a class specified in an Order under this Article if, in the course of a business carried on by that person –

(a) substantial quantities of medicinal products of that description (that is to say, quantities exceeding those required for distribution as samples) were exported or procured to be exported during the period of 24 months ending with the day on which Article 17 comes into force; and

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

(5) Articles 18 and 26 shall have effect in relation to paragraph (4) as they have effect in relation to Article 17(2) to (5).

(6) Where a person is entitled to the grant of a licence of right by reason that paragraph (4) has effect in relation to him or her, he or she shall be entitled to the grant of a product licence; but, subject to paragraph (7), the licence shall be granted so as not to extend to medicinal products of any description other than those in respect of which the conditions specified in that paragraph are proved to the reasonable satisfaction of the Minister to have been fulfilled, and shall be limited to exporting, or procuring the exportation of, medicinal products.

(7) Article 27(5) shall have effect in relation to the grant of a licence of right in accordance with paragraph (6) as the said paragraph (5) has effect in relation to the grant of such a licence in accordance with paragraph (1) of that Article.

(8) In relation to any application for a licence of right which is made by virtue of Article 26, as applied by paragraph (5), Article 28 shall have effect subject to such modifications as may be prescribed.

49 Certificates for exporters of medicinal products

On the application by any person who proposes to export medicinal products of any description, the Minister may issue to him or her a certificate containing any such statement relating to medicinal products of that description as the Minister may consider appropriate having regard to –

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

(b) this Law and to any licence granted or other thing done by virtue of this Law.

PART 4

FURTHER PROVISIONS RELATING TO DEALING WITH MEDICINAL PRODUCTS

50 General sale lists

(1) The Minister may by Order specify descriptions or classes of medicinal products as being products which in the Minister's 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 Article which is for the time being in force.

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

Subject to any exemption conferred by or under this Part of this Law, no person shall, in the course of a business carried on by him or her, sell by retail, offer or expose for sale by retail, or supply in circumstances corresponding to retail sale, any medicinal product which is not a medicinal product on a general sale list, unless –

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

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

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

52 Sale or supply of medicinal products on general sale list

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

(2) The place at which the medicinal product is sold, offered, exposed or supplied as mentioned in paragraph (1) must be premises of which the person carrying on the business in question is the occupier and which the person is able to close so as to exclude the public, unless the product is a veterinary drug.

(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 paragraph (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 purpose of this Article.

53 Prohibition of sale of medicinal products from automatic machines

No person shall sell, or offer or expose for sale, any medicinal product by means of an automatic machine.

54 Exemptions for doctors, dentists and veterinary surgeons

(1) The restrictions imposed by Articles 51 and 52 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 hers or to a person under whose care such a patient is; or

(b) in the course of the business of a hospital or such other place as may be prescribed, where the product is sold, offered for sale or supplied for the purpose of being administered (whether in the hospital or other place or elsewhere) in accordance with the directions of an appropriate practitioner.[24]

(2) The restrictions imposed by Articles 51 and 52 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 Minister for the purposes of this paragraph, where the product is sold or supplied by a registered nurse in the course of his or 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 Minister for the purposes of this paragraph, where the product is sold or supplied by a certified midwife in the course of the certified midwife's professional practice.

(3) The restrictions imposed by Articles 51 and 52 do not apply to the sale, offer for sale, or supply of a medicinal product by a veterinary surgeon for administration by the veterinary surgeon or under his or her direction to an animal or herd which is under his or her care.

55 Exemptions in respect of herbal remedies

(1) Subject to the following provisions of this Article, the restrictions imposed by Articles 51 and 52 do not apply to anything done at premises of which the person carrying on the business in question is the occupier and which he or she 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 paragraph (1), the restrictions in Articles 51 and 52 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 or her own judgment as to the treatment required.

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

56 Power to prescribe further exemptions

(1) The Minister may by Order provide that Article 51 or 52 or both those Articles, shall have effect subject to such exemptions (other than those for the time being having effect by virtue of Articles 54 and 55) as may be specified in the Order.

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

57 Medicinal products on prescription only[25]

(1) The Minister may by Order specify the following matters for the purposes of this Article –

(a) descriptions, or classes, of medicinal products;

(b) descriptions, or classes, of persons (being doctors, dentists, veterinary surgeons, registered nurses, certified midwives or other practitioners or other persons), being persons that the Minister thinks fit to be appropriate practitioners.

(2) Subject to the following provisions of this Article –

(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 under paragraph (1)(a) except in accordance with a prescription given by an appropriate practitioner; and

(b) no person shall administer (otherwise than to himself or herself) a medicinal product of a description, or falling within a class, specified under paragraph (1)(a) unless the person is –

(i) an appropriate practitioner, or

(ii) a person acting in accordance with the directions of an appropriate practitioner.

(3) Paragraph (2)(a) shall not apply –

(a) to the sale or supply of a medicinal product, to a patient of his or hers, by a person who is an appropriate practitioner other than a veterinary surgeon; or

(b) to the sale or supply of a medicinal product, for administration to an animal or herd under his or her care, by a veterinary surgeon who is an appropriate practitioner.

(4) Without prejudice to paragraph (3), an Order made under paragraph (1) may include provision for one or more of the following matters –

(a) that paragraph (2)(a) or (b), or both those sub-paragraphs, shall have effect subject to such exemptions as may be specified in the Order;

(b) that, for the purpose of paragraph (2), a medicinal product shall not be taken to be –

(i) sold or supplied in accordance with a prescription given by an appropriate practitioner, or

(ii) administered by an appropriate practitioner or a person acting in accordance with the directions of an appropriate practitioner,

unless such conditions or limitations as are specified by the Order are complied with in relation to any of the following matters –

(A) the relevant classes of appropriate practitioner,

(B) the relevant classes of medicinal product,

(C) the sale, supply, use or administration, of the medicinal product,

(D) the prescription,

(E) any other matter that the Minister thinks fit.

(5) Any exemption conferred by an Order in accordance with paragraph (4)(a) may be conferred subject to such conditions or limitations as may be specified in the Order.

58 Special provisions in relation to new medicinal products

(1) The following provisions of this Article shall have effect where an Order under Article 57 is made so as to apply to all medicinal products which fall within a class specified in the Order and are of a description in respect of which the following conditions are fulfilled, that is to say, that –

(a) medicinal products of that description are not effectively on the market in Jersey;

(b) a product licence granted under Part 3 or a United Kingdom product licence or marketing authorization having effect for the purposes of this Law (whether before, on or after the date on which the Order comes into operation) applies to medicinal products of

that description (whether it also applies to medicinal products of any other description or not); and

(c) before the grant of that licence or authorization or the date on which it came into effect, as the case may be, no product licence had been granted or was in effect which was applicable to medicinal products of that description.[26]

(2) Where such an Order is made in accordance with paragraph (1) –

(a) the restrictions imposed by Article 57(2) shall not apply by virtue of the Order to medicinal products of any description except during a period beginning with the date which, in relation to medicinal products of that description, is the relevant date and of such duration from that date as may be specified in the Order;

(b) in Article 57(4)(a) the reference to exemptions specified in the Order shall, in relation to that Order, be construed as including a reference to any exemption specified in a direction given by the Minister and relating to medicinal products of a particular description specified in that direction.

(3) In paragraph (2)(a) the "relevant date", in relation to medicinal products of any description to which an Order made under paragraph (1) applies, means the date on which the Order comes into operation, or the date on which the product licence applicable to medicinal products of that description comes into operation, whichever is the later.

59 Restricted sale, supply and administration of certain medicinal products

(1) Subject to the following provisions of this Article, the Minister may by Order 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 Order or falling within a class so specified, unless –

(a) the person is a practitioner holding a certificate issued for the purposes of this Article by the Minister 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) the person 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 Order made under this Article may provide that no person shall administer (otherwise than to himself or herself) a medicinal product of a description specified in the Order, or falling within a class so specified, unless he or she is such a practitioner as is mentioned in paragraph (1)(a) or a person acting in accordance with the directions of a practitioner.

(3) The powers conferred by the foregoing provisions of this Article 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 Minister 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 Order made under this Article 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.

(5) Any such Order shall include provision as to the grant, duration, renewal, suspension and revocation of certificates for the purpose of this Article including provision for affording –

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

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

an opportunity of appearing before and being heard by the Minister or of making representations in writing to the Minister with respect to that proposal.

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

60 Special restrictions on persons to be supplied with medicinal products

The Minister may by Order 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 Order that, subject to such exceptions as may be so specified, no person –

(a) being the holder of a product licence or a United Kingdom product licence or a marketing authorization which has effect for the purposes of this Law; or

(b) in the course of business carried on by the person 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 Order applies to any person who does not fall within a class specified in the Order.[27]

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

(1) Subject to the following provisions of this Article, the Minister, where it appears to him or her to be necessary to do so in the interests of safety, may by Order –

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

(b) prohibit the sale or supply, or the importation, of animal feeding stuffs in which medicinal products of any description, or falling within any class, specified in the Order have been incorporated, or (in such manner as may appear to it to be sufficient to identify the feeding stuffs in question) designate particular animal feeding stuffs in which medicinal products have been incorporated and prohibit the sale or supply, or the importation, of those particular feeding stuffs.

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

(3) No Order made under this Article shall come into effect until at least 3 months have elapsed since the making of the Order.

(4) Paragraph (3) shall not apply where the Minister is of opinion that the Order should have immediate effect to avoid serious danger to health, whether of human beings or animals.

62 Adulteration of medicinal products

No person shall –

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

(b) sell or supply, or offer or expose for sale or supply, or have in his or her 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.

63 Protection of purchasers of medicinal products

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

(2) For the purposes of this Article 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) Paragraph (1) shall not be taken to be contravened by reason only that a medicinal product contains some non-injurious 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) Paragraph (1) shall not be taken to be contravened by reason only that a substance has been added to, or abstracted from, the medicinal product, if it is proved that –

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

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

(5) Where a medicinal product is sold or supplied in pursuance of a prescription given by an appropriate practitioner, the foregoing provisions of this Article shall have effect as if –

(a) any reference to sale included a reference to supply and (except as provided by sub-paragraph (b)) 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 paragraph (1), for the words "demanded by the purchaser", there were substituted the words "specified in the prescription".[28]

64 Compliance with standards specified in monographs in certain publications

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

(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 an appropriate practitioner in which the product required is described by, or by express reference to, a particular name,

if that name is or is an approved synonym for, a name at the head of the relevant monograph and the product does not comply with the standard specified in that monograph.[29]

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

(3) Where a medicinal product is sold or supplied in the circumstances specified in paragraph (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 said paragraph the product shall be taken not to comply with the standard specified in the relevant monograph if, insofar as it consists of that ingredient, it does not comply with the standard so specified.

(4) Subject to paragraph (7), in this Article –

"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 paragraph (1) or (2);

"publication" means one of the following, that is to say, the British Pharmacopoeia, the European Pharmacopoeia, the British Pharmaceutical Codex, the British Veterinary Codex and any compendium published under Part VII of the Medicines Act;

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

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

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

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

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

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

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

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

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

(6) For the purposes of this Article 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

amendments, additions or deletions made to it up to the time referred to in paragraph (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 or 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 Article to compliance with the standard specified in a monograph shall be construed accordingly.

65 Further powers to regulate dealings with medicinal products

(1) The Minister may prescribe such requirements as the Minister considers necessary or expedient with respect to any of the following matters, that is to say –

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

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

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

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

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

(f) the safekeeping of medicinal products;

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

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

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

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

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

(2) Without prejudice to the generality of paragraph (1) Orders made under that paragraph may prescribe requirements in respect of –

(a) the construction, layout, 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.

66 Offences under Part 4

(1) The following provisions of this Article shall have effect subject to Articles 104 and 105.

(2) Any person who contravenes any of the following provisions of this Part, that is to say, Article 51, 57, 62, 63 or 64 or who contravenes any Order made under Article 59, 60 or 61 shall be guilty of an offence.

(3) 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 medicinal product, knowing or having reasonable cause to suspect that it was sold, supplied or imported in contravention of an Order under Article 61, shall be guilty of an offence.

(4) Any person guilty of an offence under paragraph (2) or (3) shall be liable to a fine or to imprisonment for a term not exceeding 2 years or to both.

(5) Any person who contravenes Article 52 or 53 shall be guilty of an offence and liable to a fine not exceeding level 2 on the standard scale.

(6) Any Order made under Article 65 may provide that any person who contravenes the Order shall be guilty of an offence and liable to a fine not exceeding level 3 on the standard scale or such lesser sum as may be specified in the Order.

67 Disqualification on conviction of certain offences

(1) Where a person is convicted of an offence under Article 66(6) in respect of any premises used for carrying on a retail pharmacy business, then on the application of the Minister, the court by or before which he or she was convicted may (subject to the following provisions of this Article) make an order disqualifying the person from using those premises for the purposes of such a business for such period, not exceeding 2 years, as may be specified in the order.

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

(a) the gravity of the offence of which the person has been convicted;

(b) the unsatisfactory nature of the premises; or

(c) any offences under Article 66(6) of which the person has previously been convicted.

(3) No order under this Article shall be made against a person unless the Minister has, not less than 14 days before the date of the hearing, given the person notice in writing of the Minister's intention to apply for such an order to be made against the person.

(4) If, while an order under this Article 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 that person he or she shall be guilty of an offence and liable to a fine in respect of each day when the offence continues.[30]

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

(6) On any application made under paragraph (5) the court may revoke or vary the order as mentioned in that paragraph 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 paragraph shall be entertained if it is made within 3 months from the date of the refusal.

(7) The court shall have power to order the applicant to pay the whole or any part of the costs of the application.

PART 5

PHARMACIES

68 General provisions

(1) In this Part the "board", in relation to a body corporate, means the body of persons controlling the body corporate by whatever name called.

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

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

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

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

(3) Subject to any Order made under Article 72, 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 Article 80 –

(a) that person (or, if the business is carried on by a partnership, each of the partners) is a pharmacist and the conditions specified in Article 69 are fulfilled in relation to the business;

(b) that person is a body corporate and the conditions specified in Article 70 are fulfilled in relation to the business; or

(c) that person is a representative of a pharmacist as defined in Article 71 and the conditions specified in paragraph (2) of that Article are fulfilled in relation to the person and in relation to the business and the period applicable in accordance with paragraph (3) of that Article has not expired.

69 Business carried on by individual pharmacist or by partners

(1) Subject to paragraph (2), the conditions referred to in Article 68(3)(a) 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) the person's name and certificate of registration or those of the other pharmacist, as the case may be, are conspicuously exhibited.

(2) In relation to a business carried on by a partnership, paragraph (1) shall have effect as if –

(a) in sub-paragraph (a) of that paragraph, for the word "person", there were substituted the words "one or more of the partners"; and

(b) in sub-paragraph (b) of that paragraph, for the words "the person's name, and certificate of registration", there were substituted the words "the name and certificate of registration of the partner (or, if more than one, of each partner) exercising personal control at those premises as mentioned in sub-paragraph (a)".

(3) In this Article and in Articles 70 and 71 "certificate of registration" means a certificate issued under Article 8 of the Pharmacists and Pharmacy Technicians (Registration) (Jersey) Law 2010 or deemed, by an Order made under Article 29(c) of that Law, to have been issued under that Article.[31]

70 Bodies corporate

(1) The conditions referred to in Article 68(3)(b) 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 paragraph (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 (whether the person is the superintendent or some other person) are conspicuously exhibited.

(2) The requirements referred to in paragraph (1) in relation to a superintendent are that –

(a) the superintendent is a pharmacist and is resident in Jersey;

(b) a statement in writing signed by the superintendent, and signed on behalf of the body corporate, specifying the superintendent's name and stating whether he or she is a member of the board of that body or not, has been sent to the Minister; and

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

71 Representative of pharmacist in case of death or disability

(1) This Article shall have effect where a pharmacist carries on a retail pharmacy business and –

(a) the pharmacist dies;

(b) the pharmacist enters into any composition or arrangement with his or her creditors or otherwise becomes bankrupt within the meaning of Article 8 of the Interpretation (Jersey) Law 1954;

(c) a delegate has been appointed for the pharmacist; or

(d) the pharmacist has decisions made on his or her behalf in relation to his or her property and affairs, by a person exercising authority to do so conferred by a lasting power of attorney under Part 2 of the Capacity and Self-Determination (Jersey) Law 2016,

and a representative of the pharmacist thereafter carries on his or her business.[32]

(2) The conditions referred to in Article 68(3)(c) are that the name and address of the representative, and the name of the pharmacist whose representative he or she is, have been notified to the Minister 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 or her name and certificate of registration are conspicuously exhibited.

(3) The period referred to in Article 68(3)(c) –

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

(b) in a case within paragraph (1)(b), is a period of 3 years from the date of the composition or arrangement or the date on which he or she becomes bankrupt;

(c) in a case falling within paragraph (1)(c), is a period of 3 years from the date of the appointment of the delegate;

(d) in a case falling within paragraph (1)(d), is a period of 3 years from the date on which the person on whom authority is conferred by the lasting power of attorney commenced to exercise that authority,

or, in any such case, is such longer period as, on the application of the representative, the Minister, having regard to all the circumstances of the case, may direct.[33]

(4) In this Article "representative" –

(a) in relation to a pharmacist who has died, means his or her executor or administrator and, in respect of a period of 3 months from the date of his or her death, if he or she has died leaving no executor who is entitled and willing to carry on the business, includes any person beneficially interested in his or her estate;

(b) in a case falling within paragraph (1)(b) means the Viscount or any person appointed under the bankruptcy or composition or arrangement to carry on the business;

(c) in a case falling within sub-paragraph (c) of that paragraph means the delegate; or

(d) in a case falling within paragraph (1)(d) means the person on whom authority is conferred by the lasting power of attorney. [34]

72 Power to extend or modify conditions

(1) The Minister may by Order add to, revoke or vary any of the provisions of Articles 69 to 71, so as either –

(a) to modify, or provide new conditions in substitution for, the conditions referred to in any of the sub-paragraphs of Article 68(3); or

(b) for the purposes of any of those sub-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 paragraph (1) may be made either generally or in relation to any particular circumstances specified in the Order.

(3) Any Order made under this Article may provide that Article 68(2) or (3) shall have effect subject to such exceptions or modifications as appear to the Minister to be necessary or expedient in consequence of the provision made by the Order in accordance with paragraph (1).

(4) Where an Order under this Article is in force, any reference to Article 68 in any other enactment as amended by this Law shall be construed as a reference to that Article as modified by the Order.

73 Registered pharmacies[35]

In this Law "registered pharmacy" means premises for the time being entered in the register required to be kept under Article 74.

74 Registration of premises

(1) The Minister shall keep a register for the purposes of this Article (in this Part of this Law referred to as the "register") and subject to the following provisions of this Article, enter in the register any premises in respect of which an application is made under this Article.

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

(3) If it appears to the Minister that in a material respect the premises do not comply with the requirements of any Order made under Article 65, and accordingly the Minister proposes to certify that the premises are unsuitable for registration under this Article, the Minister shall –

(a) within 60 days of receipt of the application serve on the applicant a notice stating the Minister's proposals and the reasons for them; and

(b) before determining the application, afford the applicant the opportunity of being heard by the Minister or of making representations to the Minister in writing.

(4) The Minister shall not refuse to register any premises under this Article except after consultation with the Advisory Council.

(5) Any person aggrieved by the refusal of the Minister to register any premises in pursuance of this Article may, within 14 days of receipt of the notice of refusal, appeal to the Royal Court against the decision on the grounds that, having regard to all the circumstances of the case, the decision was unreasonable, and the decision of the Court shall be final and without further appeal.

(6) Notwithstanding anything in the foregoing provisions of this Article, the Minister shall not register any premises in pursuance of this Article unless it is shown to the Minister's satisfaction that –

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

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

75 Supplementary provisions as to registration of premises

(1) Where a change occurs in the ownership of a retail pharmacy business carried on at any premises registered in pursuance of Article 74, the registration of the premises under that Article –

(a) if the change occurs on the death of the person carrying on the business, or, in the case of a partnership, on the death of one of the partners, shall become void at the end of the period of the 3 months from the date of the death; and

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

(2) Where Article 73(2) has effect in relation to any premises, an application for the premises to be entered in the register may be made in the prescribed manner at any time before the end of the period of one year mentioned in that paragraph; and where such an application is made by virtue of this Article, Article 74 shall not apply.

(3) Where the registration of any premises under Article 74 in respect of a business becomes void by virtue of paragraph (1), an application for the premises to be restored to the register may be made by the person who, in consequence of the change of ownership, has become the owner of the business; and where such an application is made, and it is shown to the reasonable satisfaction of the Minister either –

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

(b) that, if the premises are restored to the register, and the applicant thereafter carries on a retail pharmacy business at those premises, then as from the time when he or she begins to do so he or she will be a person lawfully conducting a retail pharmacy business,

the Minister shall restore the premises to the register.

(4) A document purporting to be a certificate signed by the Medical Officer of Health and stating that, on a specified date, specified premises were, or were not, entered in the register shall be admissible in any proceedings as evidence that those premises were, or were not, entered in the register on that date.

76 Registration fees

The Minister may, by Order, prescribe the fees payable in respect of the registration or re-registration of premises under the foregoing provisions of this Part, and any such Order may make provision for the suspension of any registration until the prescribed fees have been paid.

77 Annual return of premises

Every person who carries on a retail pharmacy business shall, in the month of January in each year, send to the Minister –

(a) a list of all premises at which the person's 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.

78 Restrictions on use of titles, descriptions and emblems

(1) Subject to Article 79, 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 paragraph (2) are fulfilled.

(2) The conditions referred to in paragraph (1) are –

(a) in the case of an individual, that he or she is a person lawfully conducting a retail pharmacy business (either alone or as a member of a partnership) and that he or she 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 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 Article 70(1) is a member of the board of the body corporate.

(3) No person shall, in connection with a business carried on by him or her which consists of or includes the retail sale of any goods, or the supply of any goods in circumstances corresponding to retail sale, use the description "pharmacy" except in respect of a registered pharmacy or in

respect of the pharmaceutical department of a hospital or such other place as may be prescribed.

(4) No person –

(a) who is not a pharmacist shall take or use any of the following titles, that is to say, pharmaceutical chemist, pharmaceutist, pharmacist, member of the Royal Pharmaceutical Society of Great Britain and Fellow of the Royal Pharmaceutical Society of Great Britain; and

(b) without prejudice to sub-paragraph (a), shall take or use any of those titles in connection with a business carried on (whether by him or her 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 such other place as may be prescribed.

(5) No person shall, in connection with any business, use any title, description or emblem likely to suggest –

(a) that the person possesses any qualification with respect to the sale, manufacture or assembly of medicinal products which he or she 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.

(6) For the purposes of paragraph (5), 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.

(7) Where a person is lawfully conducting a retail pharmacy business as being a representative of a pharmacist in the circumstances specified in Article 68(3)(c), paragraphs (4) to (6) 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 could have used in accordance with those paragraphs.

79 Provision for modifying or extending restrictions under Article 78

(1) The Minister may by Order provide that any of the restrictions imposed by Article 78 shall cease to have effect, or shall have effect subject to such exceptions as may be specified in the Order.

(2) Notwithstanding paragraph (1), any Order under that paragraph may impose such further restrictions or other requirements with respect to the use of titles, descriptions and emblems as may be specified.

80 Disqualification and removal of premises from register

(1) Where a body corporate carries on a retail pharmacy and –

(a) that body is convicted of an offence under this Law, the Poisons Law or the Misuse of Drugs (Jersey) Law 1978; or

(b) any member of the board or any officer of or person employed by that body is convicted of any offence, or has been guilty of misconduct, and the offence or misconduct is such as is in the opinion of the Minister renders him or her, or would if he or she were a pharmacist render him or her, unfit to be a pharmacist,

then, subject to the following provisions of this Article, the Minister, after inquiring into the case, may direct that the body corporate shall be disqualified for the purposes of this Part for such period as the Minister may determine.[36]

(2) Subject to paragraph (3), where a representative, or a person employed by a representative in the business referred to in Article 71(1) –

(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 Minister renders him or her, or would if he or she were a pharmacist render him or her, unfit to be a pharmacist, the Minister may direct that the representative shall be disqualified for the purposes of this Part.

(3) The Minister shall not give a direction under paragraph (1), in a case falling within sub-paragraph (b), and shall not give a direction under paragraph (2) unless –

(a) one or more of the facts specified in paragraph (4) are proved to the satisfaction of the Minister; and

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

(4) The facts referred to in paragraph (3)(a) are –

(a) that the offence or misconduct in question was instigated or connived at by the board or by a member of the board, or by the representative, as the case may be;

(b) that, in the case of a body corporate, a member of the board, or an officer of or person employed by the body corporate, had, at some time within 12 months before the date on which the offence or misconduct in question occurred, been guilty of a similar offence or similar misconduct and that the board had, or with the exercise of reasonable care would have had, knowledge of that previous offence or misconduct;

(c) that, in the case of the representative, the representative or a person employed by the representative had, at some time within 12 months before the date on which the offence or misconduct in question occurred, been guilty of a similar offence or similar

misconduct and (where it was a similar offence or similar misconduct on the part of an employee) that the representative had, or with the exercise of reasonable care would have had, knowledge of that previous offence or misconduct;

(d) if the offence or misconduct in question is a continuing offence or continuing misconduct, that the board, or the representative, had, or with the exercise of reasonable care would have had, knowledge of its continuance;

(e) in the case of an offence in respect of a contravention of this Law or the Poisons Law, that the board, or the representative, had not exercised reasonable care to secure that the enactment was complied with.[37]

(5) Where the Minister gives a direction under this Article, the Minister shall forthwith notify the body corporate, representative or other person, as the case may be, and no such direction shall take effect until after the expiration of a period of one month following the notification.

(6) Any person affected by any such direction given under this Article may appeal against the direction to the Royal Court within one month of receiving notice of the direction, and in any such case, the direction shall not take effect until the appeal has been determined or withdrawn.

(7) Where the Royal Court upholds a direction given under this Article, the Minister may remove from the register all or any of the premises at which the body corporate, representative or other person, as the case may be, carries on a retail pharmacy business for such period as the Minister thinks fit.

(8) A direction given under this Article may be revoked at any time by the Minister.

81 Offences under Part 5

Any person who contravenes –

(a) Article 77;

(b) Article 78; or

(c) any Order made under Article 79(2),

shall be guilty of an offence and liable to a fine not exceeding level 2 on the standard scale.

PART 6

CONTAINERS, PACKAGES AND IDENTIFICATION OF MEDICINAL PRODUCTS

82 Labelling and marking of containers and packages

(1) The Minister may make Orders imposing such requirements as, for the purposes specified in paragraph (2), the Minister 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 paragraph (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.

(3) No person shall, in the course of a business carried on by the person, sell or supply, or have in his or her possession for the purpose of sale or supply, any medicinal product in such circumstances as to contravene any requirements imposed by an Order made under this Article 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 or her, sells or supplies a medicinal product to which the requirements are applicable without its being enclosed in a container shall, except insofar as the Order otherwise provides, be taken to contravene those requirements as if the person had sold or supplied it in a container not complying with those requirements.

(5) Without prejudice to the foregoing provisions of this Article, no person shall, in the course of a business carried on by him or her, sell or supply, or have in his or her 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.

83 Leaflets

(1) The Minister may by Order impose such requirements as, for any of the purposes specified in Article 82(2) the Minister 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 or her, supply with any medicinal product, or have in his or her possession for the purpose of so supplying, a leaflet which contravenes any requirements imposed by an Order under this Article.

(3) Without prejudice to the foregoing provisions of this Article, no person shall, in the course of a business carried on by him or her, supply with a

medicinal product of any description, or have in his or her 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.

84 Requirements as to containers

(1) The Minister may by Order prohibit the sale or supply of medicinal products otherwise than in containers which comply with such requirements as the Minister considers necessary or expedient for the purposes specified in Article 82(2) or for preserving the quality of the products and in particular, any such Order may 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 or her, sell or supply, or have in his or her possession for the purpose of sale or supply, any medicinal product in such circumstances as to contravene any requirements imposed by an Order under this Article which are applicable to that product.

85 Provisions as to medicated animal feeding stuffs

(1) Subject to paragraph (2), no person shall, in the course of a business carried on by him or her, sell or supply, or have in his or her possession for the purpose of sale or supply, any animal feeding stuff in which a 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 insofar as its composition results from the incorporation of the medicinal product in it; or

(b) is likely to mislead as to the nature or quality of the animal feeding stuff insofar as its composition so results; or

(c) is likely to mislead as to the uses or effects of animal feeding stuffs in which medicinal products of the description in question have been incorporated, insofar as any such uses or effects are attributable to the incorporation of such medicinal products,

and no person shall, in the course of a business carried on by him or her, supply with any such animal feeding stuff, or have in his or her possession for the purpose of so supplying, a leaflet which falsely describes the animal feeding stuff, or is likely to mislead as is mentioned in sub-paragraph (a), (b) or (c).

(2) [38]

(3) Article 2(11) shall have effect with the necessary modifications for the purpose of paragraph (1)(c).

86 Offences under Part 6

(1) Subject to Articles 104 and 105, any person who contravenes Article 82(5), 83(3) or 85(1) shall be guilty of an offence and liable to a fine or to imprisonment for a term not exceeding 2 years or to both.

(2) Any Order made under this Part may provide that any person who contravenes the Order or who contravenes Article 82(3), 83(2) or 84(2) or any of those provisions as applied by Article 85(1) shall be guilty of an offence and liable to a fine not exceeding such sum, not exceeding level 3 on the standard scale, as may be specified in the Order or to imprisonment for a term not exceeding 2 years or to both.

PART 7

PROMOTION OF SALES OF MEDICINAL PRODUCTS

87 Scope of Part 7

(1) Subject to the following provisions of this Article, 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 by inclusion in a cable broadcast service, or in any other way, and any reference to the issue of an advertisement shall be construed accordingly.[39]

(2) Notwithstanding paragraph (1), "advertisement" does not include spoken words except words forming part of a sound recording or broadcast.[40]

(3) Except as provided by Article 90, 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 under Part 3 which is applicable to medicinal products of that description;

(b) not being the holder of such a licence, is a person who, in the course of a business carried on by the person, is engaged, in relation to medicinal products of that description, in any such activities as are mentioned in Article 8(2) or (3) or 9(2) or (3); or

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

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 which consists of spoken words other than words falling within paragraph (2)(a) or (b), and any reference to making a representation shall be construed accordingly.

(6) In this Article "film", "sound recording", "broadcast" and related expressions have the same meanings as in the Intellectual Property (Unregistered Rights) (Jersey) Law 2011.[41]

88 False or misleading advertisements and representations

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

(2) Where a licence under Part 3 is in force which is applicable to medicinal products of a particular description, and, in accordance with the provisions of the licence, the purposes for which medicinal products of that description may be recommended to be used are limited to those specified in the licence, then, subject to the following provisions of this Article, any person who, being a commercially interested party, or at the request or with the consent of a commercially interested party issues, or causes another person to issue, an advertisement relating to medicinal products of that description which consists of or includes unauthorised recommendations shall be guilty of an offence.

(3) Subject to the following provisions of this Article any person who in the course of a relevant business carried on by the person, 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 an appropriate practitioner for the purpose of inducing the practitioner to prescribe or supply medicinal products of that description;

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

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

shall be guilty of an offence.[42]

(4) Where in the circumstances specified in paragraph (2) any person, in the course of a relevant business carried on by him or her, 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 paragraph (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 of this Article, shall be guilty of an offence.

(5) Where a person is charged with an offence under this Article, it shall be a defence for him or her to prove –

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

(b) where the offence charged is under paragraph (2) or (4), that he or she 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 paragraph (5), where a person is charged with an offence under this Article in respect of the issue of an advertisement, it shall be a defence for the person to prove that he or she is a person whose business it is to issue or arrange for the issue of advertisements, and that either –

(a) the person 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 layout; or

(b) not being a commercially interested party, he or she 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 or she did not know and had no reason to suspect that the issue of the advertisement would amount to an offence under this Article.

(7) For the purposes of this Article 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 Article to a false or misleading representation shall be construed in a corresponding way.

(8) The foregoing provisions of this Article shall have effect subject to Article 104.

(9) Any person guilty of an offence under this Article shall be liable to a fine or to imprisonment for a term not exceeding 2 years or to both.

(10) In this Article "unauthorised recommendations", in relation to the circumstances specified in paragraph (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.

89 Advertisements requiring consent of holder of product licence or marketing authorization[43]

(1) Where a product licence under this Law is in force, or a United Kingdom product licence or a marketing authorization has effect for the purposes of this Law, which (in each case) is applicable to medicinal products of a particular description, then, except with the consent of the holder of the licence or authorization –

(a) no commercially interested party (other than the holder of the licence or authorization) 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 Article 104, a person who contravenes the provisions of this Article shall be guilty of an offence and liable to a fine not exceeding level 2 on the standard scale.

90 Powers to regulate advertisements and representations

(1) The Minister may by Order 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 Order;

(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 Order 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 Order, or the use of any other substance or article of a description or class so specified, for any such purpose as is mentioned in sub-paragraph (b);

(d) the issue of advertisements relating to medicinal products and containing a word or phrase specified in the Order, as being a word or phrase which, in the opinion of the Minister, 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) An Order made in pursuance of paragraph (1)(b), (c) or (d) 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 Order applies for a purpose specified in the Order in accordance with sub-paragraph (b) of that paragraph or containing a word or phrase specified in the Order in accordance with sub-paragraph (d) of that paragraph, 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 Order applies;

(b) is made to a person for the purpose of inducing the person 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 Order applies; or

(c) in the case of medicinal products of a description to which the Order applies, is made to an appropriate practitioner for the purpose of inducing the practitioner to prescribe or supply medicinal products of that description or is made to a patient or client of an appropriate practitioner for the purpose of inducing the patient or client to request the practitioner to prescribe medicinal products of that description.[44]

(3) Without prejudice to the foregoing provisions of this Article, the Minister may by Order impose such requirements as, for any of the purposes specified in the next following paragraph, the Minister considers necessary or expedient with respect to any one or more of the following matters, that is to say –

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

(b) the form of any such advertisements; and

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

and any such Order may prohibit the use, in relation to medicinal products of a description specified in the Order, of advertisements of any particular kind so specified.

(4) The purposes referred to in paragraph (3) are –

(a) securing that adequate information is given with respect to medicinal products;

(b) preventing the giving of misleading information with respect to such products;

(c) promoting safety in relation to such products.

(5) Any prohibition imposed by an Order under this Article may be a total prohibition or may be imposed subject to such exceptions as may be specified in the Order.

(6) Any Order made under this Article may provide that any person who contravenes the Order shall be guilty of an offence and liable to a fine not exceeding such amount, not exceeding level 3 on the standard scale, as may be specified in the Order or to imprisonment for a term not exceeding 2 years or to both.

(7) The provisions of Article 87(3) shall not have effect for the purposes of paragraph (1)(b) to (d).

91 Advertisements and representations directed to appropriate practitioners[45]

(1) No advertisement relating to medicinal products of a particular description, other than a data sheet, shall be sent or delivered to an appropriate 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 paragraph (3) are fulfilled.[46]

(2) No representation likely to promote the use of medicinal products of a particular description referred to in the representation shall be made to an appropriate 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 paragraph (3) are fulfilled.[47]

(3) The conditions referred to in paragraphs (1) and (2) 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 the practitioner at the time when the representation is made, or that such a data sheet has been sent or delivered to the practitioner not more than 15 months before the date on which the advertisement is sent or delivered or the representation is made; and

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

(4) Subject to Article 104, any person who contravenes paragraph (1) or (2) shall be guilty of an offence, and, if he or she contravenes that paragraph by not complying with the condition specified in paragraph (3)(b) shall be liable to a fine or to imprisonment for a term not exceeding 2 years or to both, and in any other case, shall be liable to a fine not exceeding level 2 on the standard scale.

(5) In this Article and in Article 92 "data sheet" means a document relating to medicinal products of a particular description, which is prepared by or on behalf of the holder of a product licence which is applicable to medicinal products of that description and which –

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

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

92 Power for Minister to require copies of advertisements

(1) The Minister may serve on any person a notice requiring the person, within such time as may be specified in the notice, to furnish to the Minister such number of copies (not exceeding 12) as may be so specified of any advertisements (including any data sheet) relating to medicinal products, or to medicinal products of a description or falling within a class so specified, which the person has issued, or has caused to be issued, within the period of 12 months ending with the date of service of the notice, and which the person 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 or her by a notice under this Article shall be guilty of an offence, and shall be liable to a fine not exceeding level 2 on the standard scale.

PART 8

MISCELLANEOUS AND SUPPLEMENTARY PROVISIONS

93 Application of Law to certain articles and substances

The Minister may by Order specify any description or class of articles or substances appearing to the Minister to be articles or substances which are not medicinal products but are manufactured, sold, supplied, imported or exported for use wholly or partly for a medicinal purpose, and may by the Order direct that, subject to such exceptions and modifications as may be specified in the Order, such provisions of this Law 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.

94 Application of Law to certain other substances which are not medicinal products

(1) The Minister may by Order specify any substance appearing to the Minister 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 of this Law 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 paragraph (1) may be exercised in relation to a class of substances if it appears to the Minister that the conditions specified in sub-paragraph (a) or (b) of that paragraph are fulfilled in relation to all substances falling within that class.

95 Extension of references to carrying on business

(1) The Minister may by Order direct that such provisions of this Law as may be specified in the Order, insofar as they relate to things done by a person in the course of a business carried on by the person, 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 paragraph (1), the Minister may by Order direct that such provisions of this Law as may be specified in the Order, insofar as they relate to things done by a person in the course of a business carried on by him or her, 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.

96 Rights of entry

(1) Subject to the following provisions of this Article, any person duly authorized in writing by the Minister shall, on production, if required, of his or her authority have a right at any reasonable time to enter any premises –

(a) for the purpose of ascertaining whether there is or has been, on or in connection with those premises, any contravention of any provisions of this Law or of any Order made under this Law; or

(b) generally for the purposes of the performance by the Minister of his or her functions under this Law or under any such Order.

(2) Any person duly authorized in writing by the Minister shall, on production, if required, of his or her authority, have a right at any reasonable time –

(a) to enter any ship, aircraft or hover vehicle for the purpose of ascertaining whether there is in the ship, aircraft or vehicle any substance or article imported in contravention of any provisions of this Law or of any Order made under this Law;

(b) to enter any vehicle other than a hover vehicle, any stall or place other than premises, or any home-going ship, for any purpose for which under paragraph (1) the person so authorized would have a right to enter any premises.

(3) Without prejudice to paragraph (1), any person duly authorized in writing by the Minister shall, on production, if required, of his or her authority, have a right at any reasonable time to enter any premises occupied by an applicant for a licence or certificate under Part 3 of this Law 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 foregoing provisions of this Article unless 24 hours notice of the intended entry has been given to the occupier.

(5) If the Bailiff, on information given on oath, is satisfied that there are reasonable grounds for a duly authorized person to enter any premises for any of the purposes specified in this Article, 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 issue a warrant authorizing the person named therein, to enter the premises, if need be by force.

(6) Paragraph (5) shall have effect in relation to entering any ship, aircraft, vehicle, stall or place which may be entered under paragraph (2) as it has effect in relation to entering any premises, as if 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 Article shall continue in force for a period of one month.

(8) In this Article "home-going ship" means a ship engaged exclusively in voyages which start and end in Jersey and do not involve calling at any place outside Jersey.

97 Power to inspect, take samples and seize goods and documents

(1) For the purpose of ascertaining whether there is or has been a contravention of this Law or of any Order made thereunder any person duly authorized in writing in that behalf by the Minister (hereinafter referred to as an "authorized officer") shall have a right to inspect –

(a) any substance or article appearing to him or her to be a medicinal product;

(b) any article appearing to him or her 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;

(c) any plant or equipment appearing to him or her to be used or intended to be used in connection with the manufacture or assembly of medicinal products, and any process of manufacture or assembly of any medicinal products and the means employed, at any stage in the process of manufacture or assembly, for testing the materials after they have been subjected to those processes.

(2) Where for the purpose specified in paragraph (1) an authorized officer requires a sample of any substance or article appearing to him or her 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,

the authorized officer shall (if he or she does not obtain the sample by purchase) have a right to take a sample of that substance or article.

(3) For the purposes specified in paragraph (1), an authorized officer 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 or her possession or under his or her control;

(b) to take copies of, or of any entry in, any book or document produced in pursuance of sub-paragraph (a).

(4) An authorized officer shall have a right to seize and detain any substance or article which he or she 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 or she 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 paragraph (4), an authorized officer may, so far as is reasonably necessary in order to secure that the provisions of this Law and any 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 or her to do so.

(6) Where an authorized officer seizes any substance or article (including any document) in the exercise of such a right as is specified in paragraph (4), he or she 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 foregoing provisions of this Article, an authorized officer 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 3 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 paragraph an authorized officer exercises any such right as is specified in paragraph (4), he or she shall be subject to the duty imposed by paragraph (6).

(8) The Schedule shall have effect with respect to samples obtained by an authorized officer on behalf of the Minister for the purposes of this Law.

98 Application of sampling procedure to substance or article seized under Article 97

(1) This Article shall have effect where an authorized officer seizes a substance or article (other than a document) in the exercise of such a right as is specified in Article 97(4) (including that paragraph as applied by paragraph (7) of that Article).

(2) If any person who in accordance with paragraph (6) of that Article is entitled to be informed of the seizure so requests, either at the time of the seizure or at any subsequent time, not being later than 21 days after the person is informed of the seizure, then, subject to the next following paragraph, the authorized 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 the person considers more appropriate having regard to the nature of that substance or article.

(3) An authorized officer shall not be required by virtue of paragraph (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) The Schedule shall have effect in relation to a sample which has been obtained in pursuance of this Part.

(5) The Minister may by Order provide that, in relation to substances or articles of any such description as may be specified in the Order, the Schedule shall have effect subject to such exceptions and modifications as may be specified in the Order.

99 Supplementary provisions as to rights of entry and related rights

(1) Any person entering any property (that is to say, any premises, ship, aircraft, stall or place) by virtue of Article 96 (whether in pursuance of a warrant or not) may take with him or her such other person and such equipment as may appear to him or her to be necessary; and on leaving any such property which he or she has entered in pursuance of a warrant under that Article he or she 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 or she found it.

(2) Any person who –

(a) wilfully obstructs an authorized officer acting in pursuance of this Law;

(b) wilfully fails to comply with any requirement properly made to the person by an authorized officer; or

(c) without reasonable cause fails to give to an authorized officer any other assistance or information which he or she may reasonably require of that person for the purpose of the performance of his or her functions under this Law,

shall be guilty of an offence and shall be liable to a fine not exceeding level 2 on the standard scale.

(3) If any person, in giving any such information as is mentioned in paragraph (2)(c), makes any statement which he or she knows to be false, he or she shall be guilty of an offence and shall be liable to a fine or to imprisonment for a term not exceeding 2 years or to both.

100 Analysis of samples in other cases

(1) A person who, not being an authorized officer, has purchased a medicinal product may submit a sample of it for analysis to the Official Analyst.

(2) Paragraphs 2 to 12 of the Schedule shall have effect in relation to a person proposing to submit a sample in pursuance of the preceding paragraph, as if in those paragraphs any reference to the sampling officer were a reference to that person.

(3) Subject to the following provisions of this Article, the Official Analyst shall as soon as practicable analyse the sample or cause it to be analysed by some other person under the Official Analyst's direction.

(4) The Official Analyst may demand payment in advance of such fee as may be prescribed, and, if the Official Analyst demands such payment, he or she shall not be required to analyse the sample or cause it to be analysed until the fee has been paid.

(5) The Official Analyst shall issue a certificate specifying the result of the analysis to the person by whom the sample was originally submitted.

(6) Any certificate issued under paragraph (5) shall be in a form prescribed by the Minister and shall be signed by the Official Analyst but the analysis may be made by any person acting under his or her direction.

(7) Paragraphs 17 to 19 of the Schedule shall have effect in relation to a certificate issued under paragraph (5) as they have effect in relation to a certificate issued under paragraph 15 of that Schedule.

101 Liability to forfeiture under Customs and Excise Law

(1) For the purposes of the Customs and Excise Law, the importation of any goods –

(a) falling within a class specified in an Order made by the Minister for the purposes of this Article; and

(b) imported in such circumstances as are specified in that Order,

is hereby prohibited.

(2) For the purposes of Article 37 of the Customs and Excise Law 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 the Order made by the Minister for the purposes of this Article; and

(b) they are exported in such circumstances as are specified in that Order.

(3) Any class of goods specified in an Order under paragraph (1) or (2) shall be so specified as to consist exclusively of goods appearing to the Minister 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.

102 Special enforcement and sampling provisions relating to animal feeding stuffs

(1) For the purposes of the application of Articles 97, 98 and 100 in relation to animal feeding stuffs, an Order made by the Minister may provide that any of those provisions specified in the Order shall have effect subject to such modifications as may be so specified.

(2) An Order made by the Minister under this Article –

(a) may make provision as to the manner in which samples may be taken by virtue of Article 97 as modified by any Order made under paragraph (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 Article 98 as so modified, or as to the manner in which samples may be submitted for analysis by virtue of Article 100, 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 the Schedule) as to the manner in which such samples, substances and articles are to be dealt with.

(3) For the purposes of proceedings for an offence under this Law relating to animal feeding stuffs an Order under this Article 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 Order 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 paragraph, so much of any licence granted or animal test certificate issued under Part 3 as imposes any restriction or requirement by reference to the quantity to 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, Article 85(2) 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 Order may specify in relation to medicinal products of that description, or in relation to a class of medicinal products which includes products of that description.

(6) The powers conferred by paragraph (2) shall be exercisable in addition to any power exercisable by virtue of paragraph 20 of the Schedule.

(7) References in paragraphs (1) and (3) to animal feeding stuffs include a reference to any medicated feeding stuff, within the meaning of Article 2(4).

103 Restrictions on disclosure of information

(1) If any person discloses to any other person –

(a) any information with respect to any manufacturing process or trade secret obtained by him or her in premises which he or she has entered by virtue of Article 96; or

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

he or she shall, unless the disclosure was made in the performance of his or her duty, be guilty of an offence.

(2) Any person guilty of an offence under this Article shall be liable to a fine or to imprisonment for a term not exceeding 2 years or to both.

104 Contravention due to default of other person

(1) Where a contravention by any person of any provision to which this Article 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 or she 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 Article applies proves to the satisfaction of the court –

(a) that he or she 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 be acquitted of the offence.

(3) This Article applies to Articles 62 to 64, 82 to 85, and 88 to 91, and to any Order under any of those Articles.

105 Warranty (*garantie*) as defence

(1) Subject to the following provisions of this Article, in any proceedings for an offence under this Law in respect of a contravention of a provision to which this Article applies, it shall be a defence for the defendant to prove –

(a) that he or she purchased the substance or article to which the contravention relates in Jersey 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 or she 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 or she 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 or she purchased it.

(2) This Article applies to Articles 62(b), 63, 64, 82 to 84 and 85, and to any Order made under any of those Articles.

(3) A servant of the person who purchased the substance or article shall be entitled to rely on the provisions of this Article in the same way as his or

her employer would have been entitled to do if he or she had been the defendant.

(4) 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 or her to do so.

(5) For the purposes of this Article 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 Article applies.

106 Offences in relation to warranties (*garanties*) and certificates of analysis

(1) If a defendant in any such proceedings as are mentioned in Article 105(1) 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 Article 100, or under paragraph 16 of the Schedule which relates to a sample of a different substance or article,

the defendant shall be guilty of an offence.

(2) A person who, in respect of any substance or article sold by him or her in respect of which a warranty might be pleaded under Article 105, gives to the purchaser a false warranty in writing shall be guilty of an offence, unless he or she proves that when he or she gave the warranty he or she had reason to believe that the statement or description contained in it was accurate.

(3) Any person guilty of an offence under this Article shall be liable to a fine or to imprisonment for a term not exceeding 2 years or to both.

(4) In this Article and Article 105, "warranty" means a "*garantie*" in accordance with customary law.

107 Offences by bodies corporate; accessories and abettors

(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 act in any such capacity, he or she 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 Article 70(1), paragraph (1) of this Article shall have effect in relation to a person who (not being such an officer of the body corporate as is mentioned in that paragraph of this Article) –

(a) is the superintendent referred to in paragraph (1) of that Article; or

(b) at any premises where the business is carried on, is the pharmacist referred to in paragraph (1)(a) of that Article who acts under the directions of the superintendent,

as if he or she were such an officer of the body corporate as is mentioned in paragraph (1) of this Article.

(3) Without prejudice to paragraph (1) or (2), any person who knowingly or wilfully aids, abets, causes, commands, counsels or procures the commission of an offence under this Law shall be liable to be dealt with, tried and punished as a principal offender.

108 Presumptions

(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 Article 41;

(b) offering a medicinal product for sale by retail in contravention of Article 51 or 52; or

(c) offering a medicinal product for sale in contravention of Article 62(b),

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 sub-paragraph (b), that he or she 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 paragraph applies as relates to a person's having any medicinal product or animal feeding stuff in his or her 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 the person had that medicinal product or animal feeding stuff in his or her possession for the purpose of sale or supply.

(3) Paragraph (2) applies to Articles 62(b), 82(3) and (5) and 84(2) and to any of those provisions as applied by Article 85(1) and to Article 85(2) except insofar as it relates to leaflets.

(4) For the purposes of any proceedings under this Law for an offence consisting of a contravention of Article 83(2) or (3), or of so much of Article 85(1) 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 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 the person had the leaflet in his or her possession –

(a) where the offence charged relates to Article 83, for the purpose of supplying it with a medicinal product; or

(b) where the offence charged relates to Article 85, for the purpose of supplying it with animal feeding stuff in which a medicinal product has been incorporated.

109 Service of documents

Any notice or other document required by this Law to be served on any person is validly served if it is served by post or by personal service.

110 General provisions as to Regulations and Orders

(1) The Minister may make Orders for any purpose for which Orders are authorized or required to be made under this Law.

(2) Except insofar as this Law otherwise provides, any power conferred thereby to make any Regulations or Order may be exercised –

(a) either 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 case; and

(b) so as to make in relation to the cases in relation to which it is exercised –

(i) the full provision to which the power extends or any less provision (whether by way of exception or otherwise),

(ii) the same provision for all cases in relation to which the power is exercised or different provisions for different cases or classes of case, or different provisions as respects the same case or class of case for different purposes of this Law, or

(iii) any such provision either unconditionally or subject to any specified conditions.

(3) Without prejudice to any specific provision of this Law, any Regulations or Order under this Law may contain such transitional, consequential, incidental or supplementary provisions as appear to the States or the Minister, as the case may be, to be necessary or expedient for the purposes of the Regulations or Order.

(4) Before making any Order under this Law (other than an Order which, in pursuance of this Law, in the case of urgency may be made with immediate effect) the Minister shall consult with the Advisory Council and such other organisations as appear to the Minister to be representative of interests likely to be substantially affected by the Order.

(5) [48]

111 General provisions as to operation of Law

The provisions of this Law, and of any Orders made under it, shall operate cumulatively; and any exemption or exception from any of those provisions shall not be construed as conferring any exemption or exception in relation to any other of those provisions.

112 Protection of officers etc.

(1) An officer of an administration of the States for which the Minister is assigned responsibility shall not be personally liable in respect of any act done by the officer in the execution or purported execution of this Law and within the scope of the officer's employment if he or she did it in the honest belief that his or her duty under this Law required or entitled him or her to do it.

(2) Where an action has been brought against an officer of an administration of the States for which the Minister is assigned responsibility, in respect of an act done by the officer in the execution or purported execution of this Law, and the circumstances are such that the officer is not legally entitled to require the Minister to indemnify him or her, the Minister may nevertheless indemnify the officer 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 the Minister is satisfied that the officer honestly believed that his or her duty under the Law required or entitled the officer to do it.

(3) In this Article –

(a) any reference to an officer of an administration of the States for which the Minister is assigned responsibility shall be construed as including a reference to any person who, not being such an officer, is authorized to act in pursuance of this Law by the Minister; and

(b) in relation to any such person, any reference in this Article to the scope of his or her employment shall be construed as a reference to the scope of the authorization under which he or she acts.

113 Citation

This Law may be cited as the Medicines (Jersey) Law 1995.

SCHEDULE

SAMPLING

(Articles 97, 98, 100, 102, 106)

Introductory

1 This Schedule shall have effect where an authorized 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 article or substance, any contravention of the provisions of this Law or any Order made thereunder; or

(b) for any other purpose connected with the performance of the authorized officer's functions under this Law or any such Order, and the officer obtains the sample by purchase or in exercise of any power conferred by Article 97.

Division of sample

2 The officer shall forthwith divide the sample into 3 parts, each part to be marked and sealed or fastened up in such manner as its nature will permit.

3 If the sample was purchased by the officer the officer shall supply one part of the sample to the seller.

4 If the sample is of goods consigned from outside Jersey and was taken by the officer before delivery to the consignee, the officer shall supply one part of the sample to the consignee.

5 If, in a case not falling within paragraphs 3 or 4, the sample was obtained by the officer at the request or with the consent of a purchaser, the officer shall supply one part of the sample to the seller.

6 If, in a case not falling within any of paragraphs 3 to 5, the sample was taken in transit, the officer shall supply one part of the sample to the consignor.

7 In any case not falling within any of paragraphs 3 to 6 the officer shall supply one part of the sample to the person appearing to the officer to be the owner of the substance or article from which the sample was taken.

8 In every case falling within any of paragraphs 3 to 7 the 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.

9 Of the remaining parts of the sample into which the sample is divided in accordance with paragraph 2, the officer, unless the officer 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.

10 Where a sample consists of substances or articles enclosed in unopened containers, and it appears to the 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 officer may divide the sample into parts by dividing the containers into 3 lots without opening them.

11 Article 109 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.

12 If after reasonable inquiry the 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 or she may retain that part of the sample instead of supplying it.

Notice to person named on container

13

(1) Where it appears to the officer that a substance or article of which he or she has obtained a sample was manufactured or assembled by a person whose name and address in Jersey 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 foregoing provisions of this Schedule, the officer, unless he or she 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 officer; and

(b) specifying the person from whom the officer purchased it, or, if the officer obtained it otherwise than by purchase, the place from which he or she obtained it.

(2) The notice required to be served under sub-paragraph (1) shall be served before the end of the period of 3 days beginning with the day on which the sample was obtained.

Analysis or other examination of sample

14 If the officer decides to submit the sample for analysis or other appropriate examination, he or she shall submit it for analysis or other examination to the Official Analyst.

15

(1) As soon as practical after receipt of the sample, the Official Analyst 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 the Official Analyst's direction. The Official Analyst shall issue and send to the officer a certificate specifying the results obtained.

(2) Any certificate issued under this paragraph shall be in a form prescribed by the Minister and shall be signed by the Official Analyst, but the analysis may be made by a person acting under his or her direction.

16 Any person to whom a part of the sample is required to be supplied shall, on payment of such fee as may be prescribed by the Minister, be entitled to be supplied with a copy of any certificate as to the result of an analysis or examination.

Provisions as to evidence

17 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 16 shall be sufficient evidence of the facts stated in the document, unless the other party requires that the Official Analyst shall be called as a witness.

18 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 or her by the other party as being a copy of such a certificate, shall be sufficient evidence of the facts stated in the document.

19

(1) If in any such proceedings a defendant intends to produce such a certificate, or to require that the Official Analyst shall be called as a witness, a notice of his or her intention, and (where he or she intends to produce such a certificate) a copy of the certificate, shall be given to the other party at least 3 clear days before the day of the hearing.

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

Power to modify sampling provisions

20 The Minister may by Order provide that, in relation to substances or articles of any such description as may be specified in the Order, the foregoing provisions of this Schedule shall have effect subject to such exceptions and modifications as may be specified in the Order.

ENDNOTES

Table of Legislation History

Legislation	Year and No	Commencement	*Projet No (where applicable)
Medicines (Jersey) Law 1995	L.31/1995	1 January 1998 (R&O.9124)	
Criminal Procedure (Prescription of Offences) (Jersey) Law 1999	L.23/1999	23 July 1999	P.34/1999
Medicines (Amendment) (Jersey) Law 2002	L.35/2002	15 November 2002	P.77/2002
Medicines (Amendment No. 2) (Jersey) Law 2005	L.10/2005	1 December 2005	P.214/2004
States of Jersey (Amendments and Construction Provisions No. 5) (Jersey) Regulations 2005	R&O.45/2005	9 December 2005	P.59/2005
Pharmacists and Pharmacy Technicians (Registration) (Jersey) Law 2010	L.6/2010	16 May 2010	P.209/2009
Medicines (Amendment No. 3) (Jersey) Law 2011	L.24/2011	28 October 2011	P.94/2011
Intellectual Property (Unregistered Rights) (Jersey) Law 2011	L.29/2011	18 December 2012 (R&O.148/2012)	P.141/2010
European Union Legislation (Implementation) (Jersey) Law 2014	L.28/2014	31 October 2014	P.164/2013
States of Jersey (Transfer of Functions No. 8) (Miscellaneous Transfers) (Jersey) Regulations 2015	R&O.158/2015	1 January 2016	P.46/2015 (re-issue)
Dentistry (Jersey) Law 2015	L.17/2015	24 February 2016 (R&O.22/2016)	P.89/2015
Criminal Justice (Miscellaneous Provisions) (Jersey) Law 2016	L.1/2016	20 September 2016 (R&O.98/2016)	P.87/2015
Animal Health (Jersey) Law 2016	L.12/2016	29 July 2016 (Only Schedule 5 paragraph 17(a) in force) 1 February 2017 (remainder in force) (R&O.2/2017)	P.17/2016

Legislation	Year and No	Commencement	*Projet No (where applicable)
Mental Health and Capacity (Consequential Amendment and Transitional Provision) (Jersey) Regulations 2018	R&O.49/2018	1 October 2018 (R&O.51/2018)	P.48/2018
Legislation (Jersey) Law 2021	L.8/2021 (R&O.112/2021)	28 September 2021	P.26/2021

*Projets available at www.statesassembly.gov.je

Table of Renumbered Provisions

Original	Current
PART I	PART 1
1(5), (6)	spent, omitted from this revised edition
PART II	PART 2
PART III	PART 3
29(3)(j)	29(3)(i)
(k)	(j)
PART IV	PART 4
65(1)(j)	65(1)(i)
(k)	(j)
(l)	(k)
PART V	PART 5
PART VI	PART 6
PART VII	PART 7
PART VIII	PART 8
108	repealed by L.23/1999
109	108
110	109
111	110
112	111
113	112
114	spent, omitted from this revised edition
115	113
FIRST SCHEDULE	SCHEDULE
SECOND SCHEDULE	spent, omitted from this revised edition
THIRD SCHEDULE	spent, omitted from this revised edition

Table of Endnote References

[1] *This Law has been amended by the States of Jersey (Amendments and Construction Provisions No. 5) (Jersey) Regulations 2005. The amendments replace all references to a Committee of the States of Jersey with a reference to a Minister of the States of Jersey, and remove and add defined terms appropriately, consequentially upon the move from a committee system of government to a ministerial system of government*

[2] *Article 1(1)* *amended by L.35/2002, L.6/2010, L.24/2011, L.17/2015*

[3] *Article 4* *substituted by R&O.45/2005*

[4] *Article 4(2)* *amended by R&O.158/2015*

[5] *Article 7* *substituted by L.35/2002*

[6] *Article 8(1)* *amended by L.10/2005*

[7] *Article 8(2A)* *inserted by L.10/2005*

[8] *Article 19(3)* *substituted by L.35/2002*

[9] *Article 22* *substituted by R&O.45/2005*

[10] *Article 24(1)* *amended by L.35/2002*

[11] *Article 25(2)* *amended by L.28/2014*

[12] *Article 25(6)* *substituted by L.35/2002*

[13] *Article 25(7)* *substituted by L.35/2002*

[14] *Article 25(8)* *inserted by L.35/2002*

[15] *Article 29(3)* *amended by L.28/2014*

[16] *Article 31* *substituted by R&O.45/2005*

[17] *Article 33(3)* *amended by L.12/2016*

[18] *Article 41(2)* *amended by L.35/2002*

[19] *Article 41(3)* *amended by L.35/2002*

[20] *Article 42(4)* *amended by L.35/2002*

[21] *Article 44* *substituted by L.35/2002*

[22] *Article 45(1)* *amended by L.35/2002*

[23] *Article 47(2)* *amended by L.28/2014*

[24] *Article 54(1)* *amended by L.24/2011*

[25] *Article 57* *substituted by L.24/2011*

[26] *Article 58(1)* *amended by L.35/2002*

[27] *Article 60* *amended by L.35/2002*

[28] *Article 63(5)* *amended by L.24/2011*

[29] *Article 64(1)* *amended by L.24/2011*

[30] *Article 67(4)* *amended by L.1/2016*

[31] *Article 69(3)* *substituted by L.6/2010*

[32] *Article 71(1)* *amended by R&O.49/2018*

[33] *Article 71(3)* *amended by R&O.49/2018*

[34] *Article 71(4)* *amended by R&O.49/2018*

[35] *Article 73* *substituted by L.6/2010*

[36] *Article 80(1)* *amended by L.6/2010*

[37] *Article 80(4)* *amended by L.6/2010*

[38] *Article 85(2)* *deleted by L.12/2016*

[39] *Article 87(1)* *amended by L.29/2011*

[40] *Article 87(2)* *amended by L.29/2011*

[41] *Article 87(6)* *substituted by L.29/2011*

[42] *Article 88(3)* *amended by L.24/2011*

[43] *Article 89* *substituted by L.35/2002*

[44] *Article 90(2)* *amended by L.24/2011*

[45] *Article 91* *heading amended by L.24/2011*
[46] *Article 91(1)* *amended by L.24/2011*
[47] *Article 91(2)* *amended by L.24/2011*
[48] *Article 110(5)* *deleted by L.8/2021*