# LAWS OF BRUNEI

# CHAPTER 285
# MEDICINES

**S 79/2007**

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# CHAPTER 285

# MEDICINES

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SCHEDULE — DISEASES OR CONDITIONS

# MEDICINES ACT

**An Act to regulate the importation, registration, promotion, advertisement, clinical trial, transport, manufacture, storage, dispensing, and sale of medicinal products and cosmetic product**

*Commencement*:
*1st January 2008 for cosmetic products*
*[S 81/2007]*
*1st July 2010 for medicinal products*
*[S 67/2010]*

## PART 1

## PRELIMINARY

### Citation

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

(2) This Act shall commence on such date as the Minister may, with the approval of His Majesty the Sultan and Yang Di-Pertuan, appoint by notification published in the *Gazette*, and the Minister may —

*(a)* appoint one commencement date for medicinal products and a different commencement date for cosmetic products;

*(b)* appoint different commencement dates for different groups of products;

*(c)* appoint different commencement dates for different provisions of this Act; or

*(d)* adopt any combination of the foregoing alternatives.

### Interpretation

**2.** (1) In this Act, unless the context otherwise requires —

"administration" means giving or applying 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 Act

to administering a substance or article is a reference to administering it either in its existing state or after it has been dissolved or dispersed in, or diluted or mixed with, some other substance used as a vehicle;

"analysis" includes micro-biological assay;

"animal" includes any bird, fish, reptile or amphibian;

"Authority" means the Brunei Darussalam Medicines Control Authority established under section 5;

"clinical trial" means an investigation or series of investigations on persons conducted by or under the direction and supervision of persons with scientific training or experience for the purpose of finding out about, or determining the safety, effectiveness and other effects of any product;

"clinical trial import licence" has the meaning ascribed to it by sections 11 and 15, and includes any provisional licence under section 17;

"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 respectively contained in it;

"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;

"contract manufacturer" means any person who manufactures any product on the order of another person to whom a manufacturer's licence has been issued under section 15.

"cosmetic product" means any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and correcting body odours, protecting them or keeping them in good condition or all or any of those purposes;

"dentist" means a dentist registered under the Medical Practitioners and Dentists Act (Chapter 112);

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

"herbal remedy" means a medicinal product consisting of a substance produced by subjecting a plant or plants to drying, crushing or comminuting or other process, or of a mixture whose ingredients are two or more substances so produced, or of a combination of such mixture with water or such other inert substances as the Authority may, by notification published in the *Gazette*, specify;

"homeopathic medicine" means any pharmaceutical dosage form used in the homeopathic therapeutic system in which diseases are treated by the use of minute amounts of such substances which are capable of producing in healthy persons symptoms similar to those of the disease being treated;

"hospital" includes any institution for the reception and treatment of the sick and designated as a hospital by the Minister for the purposes of this Act;

"import licence" has the meaning ascribed to it by sections 11 and 15, and includes any provisional licence under section 17;

"indigenous medicine" means a system of treatment and prevention of disease established through traditional use of naturally occurring substances;

"ingredient", in relation to manufacture or preparation of a product, includes any substance of that product as manufactured or prepared;

"inspector" means an inspector appointed under section 58(1);

"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;

"licence" means a licence issued under this Act;

"licensed importer" means a person to whom an import licence has been issued under this Act;

"licensed manufacturer" means a person to whom a manufacturer's licence has been issued under this Act, and includes a contract manufacturer;

"licensed wholesaler" means a person to whom a wholesaler's licence has been issued under this Act;

"leaflets" include any written information;

"manufacture", in relation to any product includes —

*(a)* the making or assembling of the product;

*(b)* the enclosing or packing of the product in any container in a form suitable for administration or application, and the labelling of the container; and

*(c)* the carrying out of any process in the course of any of the foregoing activities,

but does not include dissolving or dispersing the product in, or diluting or mixing it with, some substance used as a vehicle for the purpose of administering it;

"manufacturer's licence" has the meaning ascribed to it by sections 11 and 15, and includes any provisional licence under section 17;

"medical practitioner" means a medical practitioner registered under the Medical Practitioners and Dentists Act (Chapter 112);

"medicinal product" has the meaning ascribed to it by section 4;

"medicine" means any substance or combination of substances presented for treating or preventing disease in human beings or animals. Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a "medicine";

"midwife" means a midwife registered under the Midwives Act (Chapter 139);

"Minister" means the Minister of Health;

"nurse" means a nurse registered under the Nurses Registration Act (Chapter 140);

"pharmacist" means a person registered under the Pharmacists Registration Order, 2001 (S 21/2001);

"plant" includes any part of a plant;

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

"product licence" has the meaning ascribed to it by sections 11 and 15, and includes any provisional licence under section 17;

"registered medicinal product" means a product registered in accordance with the provisions of this Act;

"registered pharmacy" means premises entered in the register under section 39(1);

"retail pharmacy business" means a business (not being a professional practice carried out by a practitioner) which consists of or includes the retail sale of medicinal products other than medicinal products on a general sale list;

"retail sale", in relation to a medicinal product, has the meaning ascribed to it by subsection (2)*(b)*;

"sell" includes barter, and also includes offering or attempting to sell, or receiving for sale, or having in possession for sale, or exposing for sale, or sending or delivering for sale, or causing or allowing to be sold, offered or exposed for sale;

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

"supply" includes having in possession for the purpose of supply;

"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;

"traditional medicine" means any product used in the practice of indigenous medicine, in which the medicine consist solely of one or more naturally occurring substances of a plant, animal or mineral, of parts thereof, in the unextracted or crude extract form, and a homeopathic medicine;

"veterinary surgeon" means a person registered under the Veterinary Surgeons Order, 2005 (S 30/2005);

"wholesale dealing", in relation to a medicinal product, shall have the meaning ascribed to it under subsection (2);

"wholesaler's licence" has the meaning ascribed to it by sections 11 and 15, and includes any provisional licence under section 17.

(2) In this Act, any reference to —

*(a)* selling by way of wholesale dealing is a reference to selling to a person who buys it for the purpose of selling or supplying it in the course of a business carried on by that person, except that it does not include any such sale by the person who manufactured it;

*(b)* 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 *(a)*; and

*(c)* supplying anything in circumstances corresponding to retail sale is a reference to supplying it, otherwise than by way of sale, to a person as being a person who receives it for a purpose other than that of selling or supplying.

**Non-application of Chapter 114 to medicinal products or substances**

**3.** Nothing in the Poisons Act (Chapter 114), applies to any poison which is incorporated in a medicinal product or used as a substance for a medicinal purpose and which is regulated by the provisions of this Act.

**Meaning of "medicinal product" and related expressions**

**4.** (1) Subject to the following provisions of this section, in this Act "medicinal product" means any substance or article (not being an instrument, apparatus or appliance) which is manufactured, sold, supplied, imported or exported for use wholly or mainly in either or both of the following ways —

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

*(b)* use 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 Act, "a medicinal purpose" means any one or more of the following purposes —

*(a)* treating or preventing disease;

*(b)* diagnosing disease or ascertaining the existence, degree or extent of a physiological condition;

*(c)* contraception;

*(d)* inducing anaesthesia;

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

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

*(a)* in the course of the business of the manufacturer or on behalf of the manufacturer in the course of the business of laboratory or research established 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 paragraphs *(a)*, *(b)* and *(c)*.

(4) In this Act, "medicinal product" does not include —

*(a)* substances used in dental surgery for filling dental cavities;

*(b)* bandages and other surgical dressings, except medicated dressings where the medication has a palliative or

curative function which is not limited to sterilising the dressings;

*(c)* substances and articles of such other description or classes as may be specified by order made by the Minister.

(5) Where in accordance with subsections (1) to (4), a substance or article is a medicinal product immediately after it has been manufactured, imported or exported as mentioned in subsection (1), or immediately after the first occasion on which it has been sold or supplied as mentioned in that subsection, then it shall not cease to be a medicinal product for the purposes of this Act by reason only that, at any subsequent time, it is sold, supplied, imported or exported for the use wholly or mainly in a way other than those specified in subsection (1).

(6) For the purposes of this Act, medicinal products are of the same description if —

*(a)* they are manufactured to the same specification; manufacturing methods and processes; equipment and manufacturing plant; and

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

(7) For the purposes of this Act, a document, advertisement or representation shall be taken to be likely to mislead as the uses or effects of medicinal products of a particular description if it is likely to mislead as to any of the following matters —

*(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.

PART 2

BRUNEI DARUSSALAM MEDICINES CONTROL AUTHORITY

**Establishment and membership of Authority**

**5.** (1) For the purposes of this Act, there is hereby established the Brunei Darussalam Medicines Control Authority which shall consist of —

*(a)* the Director-General of Medical Services;

*(b)* the Director-General of Health Services;

*(c)* the Director of Pharmaceutical Services;

*(d)* not less than five other members to be appointed by the Minister, at least one of whom shall be in private service.

(2) The period of appointment of members appointed under subsection (1)*(d)* shall be 3 years, but such members shall be eligible for re-appointment.

(3) Notwithstanding subsection (2), the Minister may, at any time, in his discretion, suspend or terminate the appointment of any member appointed under subsection (1)*(d)* and may appoint another person in his place or in the place of any member who retires, dies, vacates his office, or who, for the time being, is unable to act or who is absent from three consecutive meetings of the Authority without such excuse as may seem reasonable to the Minister; and every person so appointed shall hold office for the residue of the term for which his predecessor was appointed.

**Functions of Authority**

**6.** The functions of the Authority are to advise the Minister upon and to make decisions and recommendations in relation to —

*(a)* any matter related to any registration, the issue of any licence or the listing of any medicinal product;

*(b)* the amendment of the Schedule;

*(c)* the making, amendment or any revocation of any rules under this Act;

*(d)* any matter with regard to the import, export, manufacture, storage, handling, distribution, sale, supply, possession, use, labelling or disposal of medicinal products, or that the Authority thinks fit or that the Minister may refer to it;

*(e)* the establishment of sub-committees to consider specific issues, including those relating to traditional or herbal medicines, cosmetics and the like.

**Alternate member**

**7.** (1) The Minister may appoint an alternate member in respect of each member appointed under section 5(1)*(d)*.

(2) An alternate member may attend meetings of the Authority or otherwise act for the substantive member when that substantive member is temporarily unable to act.

(3) An alternate member attending any meeting of the Authority or acting for the substantive member under subsection (2) is deemed for the purposes of this Act to be a member of the Authority.

**Meetings**

**8.** (1) Subject to subsection (2), the Director-General of Medical Services shall be the Chairman of the Authority.

(2) The Director-General of Health Services shall be the alternate Chairman and shall preside at meetings of the Authority in the absence of the Chairman.

(3) The Chairman of a meeting shall have an original vote and, in the event of an equality of votes, a second or casting vote.

(4) Five members of the Authority including the Chairman shall form a *quorum*.

(5) The Authority shall meet at such times and places as the Chairman may determine.

(6) The Authority may invite any person appointed under section 9 or any other person to attend any meeting of the Authority, but such persons shall not have the right to vote at the meeting.

(7) Subject to this Act, the Authority shall regulate its own procedure.

(8) No action or proceeding of the Authority shall be questioned on the ground —

*(a)* of the existence of any vacancy in the membership, or any defect in the appointment of any person purporting to be a member of the Authority; or

*(b)* of any omission, defect or irregularity in procedure not affecting the merits of the action or proceeding.

**Advisers**

**9.** The Authority may appoint such person or persons as it may think necessary as advisers for the purpose of giving it advice when discharging any of its functions.

PART 3

REGISTRATION AND LICENSING

**Control of manufacture, sale, supply and importation**

**10.** (1) Except as otherwise provided in section 18, no person shall manufacture, sell, supply or import any medicinal product unless —

*(a)* the medicinal product is a registered product; and

*(b)* that person holds the appropriate licence required and issued under this Act.

(2) The requirement of subsection (1)*(b)* does not apply to the sale or supply by a retailer of any medicinal product on a general sale list under section 26.

(3) The provisions of subsection (1) relating to importation do not apply to any person arriving in Brunei Darussalam, who imports, as part of his personal luggage, any medicinal product meant solely for his use or for the use of his family in a quantity not exceeding that which may be reasonably required for one month's use by one person, or to any public officer importing any medicinal product in the course of his duty, or to any

person who in accordance with the written consent of the Authority, brings any medicinal product into Brunei Darussalam in transit.

(4) In subsection (3), "in transit" means taken or sent from any country or territory and brought into Brunei Darussalam by land, air, or water, whether or not landed or trans-shipped in Brunei Darussalam, for the sole purpose of being carried to another country or territory either by the same or another conveyance.

**Registration of medicinal products**

**11.** (1) The Authority may, on application made in such manner and form as it may require, register any medicinal product subject to such conditions as it may impose.

(2) Every application for the registration of a medicinal product shall be accompanied by —

*(a)* the prescribed processing fee for that type of product; and

*(b)* such documents, items, samples, particulars and other information as the Authority may require.

(3) The Authority may charge an applicant such costs as it may incur for the purposes of carrying out any laboratory investigation prior to the registration of the medicinal product.

(4) The processing fee and such costs as may be charged by the Authority under subsection (3) shall not be refundable.

(5) Any change in any document, item, sample, particulars or other information mentioned in subsection (2)*(b)* shall be notified in writing by the applicant to the Authority within 14 days from the date of such change.

(6) Subject to section 20, the period of registration of a medicinal product shall be as specified in the product licence issued under subsection (8) and where so specified the registration shall be valid till the end of the specified period.

(7) Subject to section 20, where the period of registration of a medicinal product is not specified the registration shall be valid until it is cancelled.

(8) Upon registration of a medicinal product, the Authority shall issue to the applicant a product licence.

(9) Any person who knowingly supplies any false or misleading information to the Authority in connection with an application for the registration of a medicinal product is guilty of an offence.

**Register of medicinal products etc.**

**12.** (1) The Authority shall keep and maintain a register of the medicinal products and cosmetics products.

(2) The register shall be in such form and contain such particulars as the Authority may determine.

**Declaration relating to imported medicinal products**

**13.** The Authority may require any person applying for the registration of any imported medicinal product to furnish a written declaration made by or on behalf of the manufacturer of the medicinal product that all the legal requirements governing the manufacture of such product imposed by the laws of the country or territory of manufacture have been complied with.

**Rejection of application for registration**

**14.** The Authority may, without assigning any reason, reject any application for the registration of any medicinal product.

**Licences**

**15.** (1) The Authority may, subject to the provisions of this Act, issue any of the following licences and the application therefor shall be made in such form and manner, and shall contain, or be accompanied by, such documents, items, samples, particulars and other information, as the Authority may require. The following licences shall only be issued after an inspection, except a clinical trial import licence —

*(a)* an import licence, authorising the licensee to import, store and sell by wholesale or supply the registered products from the premises specified in licence;

*(b)* a manufacturer's licence, authorising the licensee to manufacture the registered products in the premises specified in the licence and to sell by wholesale or supply the products;

*(c)* a wholesaler's licence, authorising the licensee to sell by wholesale or supply the registered products from the business premises specified in the licence;

*(d)* a clinical trial import licence, authorising the licensee to import one product for the purpose of clinical trials, notwithstanding that the product is not a registered product.

(2) If medicines products are not included together in one licence, any number of registered products may be included in any licence other than a clinical trial import licence.

(3) Subject to subsection (2), the Authority may, on application by the licensee, add to the registered products included in any licence, other than a clinical trial import licence, and make such addition or amendment to the conditions of the licence as are rendered necessary by the addition of such added products.

(4) Subject to section 20, a licence issued under this Act, other than a clinical trial import licence, shall be valid for one year.

(5) Subject to section 20, a clinical trial import licence shall be valid for such period, not exceeding 3 years from the date of issue of the licence, as may be specified in the licence.

(6) Every licence is not transferable to any other person.

**Application for licence**

**16.** (1) An application for a licence under this Act shall be made in such manner and form as the Authority may require and shall be accompanied with the prescribed processing fee.

(2) The processing fee referred to in subsection (1) shall not be refundable.

(3) The applicant for a licence shall furnish such documents, items, particulars and other information as the Authority may require.

(4) Any person who knowingly supplies any false or misleading information to the Authority in connection with an application for a licence is guilty of an offence.

**Provisional licences**

**17.** The Minister may, with the approval of His Majesty the Sultan and Yang Di-Pertuan, make rules providing for the issue of provisional licences to such persons and on such conditions as the Minister may determine.

**Exemptions and savings**

**18.** (1) The Authority may exempt from the provisions of section 10(1), any person who wishing to import any medicinal product for the purpose of research in a school of pharmacy or a research or training institution or in order to obtain samples solely for the purpose of registration.

(2) The requirement of section 10(1) as regards a licence to manufacture or supply does not apply to the dispensing, or the doing of any act falling within the definition of "manufacture" in section 2(1) which is necessary for the dispensing, of any medicine for the purpose of its being used for medical treatment by the following persons and in the following circumstances —

*(a)* a pharmacist or a person working under the immediate personal supervision of a pharmacist in a retail pharmacy; and

*(b)* a person acting in the course of his duties under the supervision of a pharmacist who is employed in a hospital or dispensary maintained by the public or private sector, or out of public funds, or by an approved charity.

(3) Section 10(1)*(a)* does not apply to any medicine manufactured by a person and in the circumstances described in subsection (2) if it was manufactured for the purpose of dispensing.

(4) The Authority may exempt from the provisions of section 10(1), any school of pharmacy or a research or training institution wishing to manufacture any medicinal product for teaching or research purposes.

(5) The Authority may exempt from the provisions of section 10(1), any person wishing to manufacture any medicinal product solely for the purpose of producing samples for clinical trials or for registration under this Act.

(6) The Authority may exempt from the provisions of section 10(1) any person wishing to manufacture or import any medicinal product solely

for the purpose of treatment of any person suffering from a life-threatening illness.

**Certification**

**19.** (1) The Authority may issue such certification on any matter relating to any product where such certification is required by any country or territory importing such a product.

(2) The prescribed fee shall be payable on the issue of such certification.

**Suspension or cancellation of registration and revocation of licence**

**20.** (1) The Authority may, at any time and without assigning any reason, suspend or cancel the registration of any medicinal product or suspend a licence under this Part for such period as it may determine or may revoke or vary the provisions of any such licence.

(2) Subject to subsection (3), any suspension or cancellation of the registration of any medicinal product under subsection (1) shall similarly and at the same time affect any product licence issued under this Act relating to that product.

(3) Notwithstanding subsection (2), where a licence issued under this Act relates to several registered medicinal products, the suspension or cancellation of the registration of any medicinal product under subsection (1) shall not affect the position of other registered medicinal products listed in that licence.

**Appeal**

**21.** Any person aggrieved by any decision of the Authority under section 20 may make a written appeal to the Minister within 14 days from the date the decision is made known to him, and any decision of the Minister made on that appeal is final.

**Offences under this Part**

**22.** (1) Any person who contravenes any of the provisions of section 10, or who is in possession of any medicinal product for the purpose of selling, supplying or exporting it in contravention of section 10, is guilty of an offence.

(2) Where any medicinal product is imported in contravention of section 10, any person who, otherwise than for the purpose of performing or exercising a duty or power imposed or conferred by or under this Act or by or under any other written law, is in possession of that product knowing or having reasonable cause to suspect that it was so imported is guilty of an offence.

(3) Any person who, when making an application under section 11 or 15, makes a statement which he knows or has reason to believe is false in a material particular is guilty of an offence.

(4) Any person guilty of an offence under subsection (1), (2) or (3) is liable on conviction to a fine not exceeding $5,000, imprisonment for a term not exceeding 2 years or both.

## PART 4

## CLINICAL TRIALS

### Clinical trials

**23.** (1) No person shall conduct any clinical trials in Brunei Darussalam without prior written approval from the Authority.

(2) The Minister may, with the approval of His Majesty the Sultan and Yang Di-Pertuan, make rules prescribing the conditions and requirements to be complied with by a person conducting clinical trials.

## PART 5

## SALES AND OTHER DEALINGS OF MEDICINAL PRODUCTS

### General sale list

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

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

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

**25.** Subject to any exemption conferred by or under this Part, no person shall sell 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 product is sold or supplied at premises on which is carried on a retail pharmacy business registered under Part 6; and

*(b)* that person is or acts under the personal supervision of a pharmacist.

**Sale or supply of medicinal products on general sale list**

**26.** Nothing in this Act shall prevent any person from selling by retail or supplying in circumstances corresponding to retail sale any medicinal product on a general sale list subject to such conditions as may be applied for the purposes of this section.

**Prohibition on sale of medicinal products from automatic machines**

**27.** No medicinal product shall be sold by means of an automatic machine, unless it is a medicinal product in the automatic machine section of a general sale list and complies with such conditions as may be applied.

**Exemptions for medical practitioner, dentists and veterinary surgeons and in respect of herbal remedies**

**28.** (1) The restrictions imposed by section 25 do not apply to the supply of a medicinal product —

*(a)* by a medical practitioner or a dentist to his patient; or

*(b)* by a hospital, where the product is supplied for the purpose of being administered in accordance with the directions of a medical practitioner or a dentist.

(2) The restrictions imposed by section 25 do not apply to the supply of a medicinal product by a veterinary surgeon for administration by him or under his direction to an animal under his care.

(3) The restrictions imposed by section 25 do not apply to anything done at premises of which the person carrying on the business in question is

the occupier and which he is able to close so as to exclude the public, and which consists of the retail sale or the supply in circumstances corresponding to retail sale of any herbal remedy where the processes to which a plant is subjected consist of drying, crushing or comminuting, with or without diluting with water.

**Power to extend or modify exemptions**

**29.** (1) The Minister may by order provide that section 25 shall have effect subject to such exemptions (other than those having effect by virtue of section 28) as may be specified in the order.

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

(3) The Minister may by order provide that section 28 shall have effect subject to such exceptions or modifications as may be specified in the order.

**Medicinal products on prescription only**

**30.** (1) The Minister may by order specify descriptions or classes of medicinal products for the purposes of this section; and, in relation to any description or class so specified, the order shall state which of the following are to be appropriate practitioners for the purposes of this section —

*(a)* medical practitioner;

*(b)* dentists;

*(c)* veterinary surgeons.

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

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

*(b)* no person shall administer (otherwise than to himself) any such medicinal product unless he is an appropriate practitioner or a

person acting in accordance with the directions of an appropriate practitioner.

(3) An order made by the Minister for the purposes of this section may provide —

*(a)* that subsection (2)*(a)* or *(b)*, or that both subsection (2)*(a)* and *(b)* shall have effect subject to such exemptions as may be specified in the order; or

*(b)* that, for the purpose of subsection (2)*(a)*, a medicinal product shall not be taken to be supplied in accordance with a prescription given by an appropriate practitioner unless such conditions imposed by the order are fulfilled.

(4) Any exemption conferred by an order in accordance with subsection (3)*(a)* may be conferred subject to such conditions as may be specified in the order.

**Prohibition of sale, supply or importation of certain medicinal products or of animal feeding stuffs incorporating such products**

**31.** (1) The Minister may, where it appears to him to be necessary to do so in the interests of a safety, by order —

*(a)* prohibit the sale, supply or importation of medicinal products of any description, or falling within any class, specified in the order;

*(b)* prohibit the sale, supply or importation of animal feeding stuffs in which medicinal products of any description, or falling within any class, specified in the order have been incorporated.

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

**Adulteration of medicinal products**

**32.** 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 the product shall be sold or supplied in that state; or

*(b)* sell or supply any medicinal product of which the composition has been injuriously affected by the addition or abstraction of any substance.

**Counterfeit medicines**

**33.** (1) Any person concerned in the manufacture, supply, donation, distribution, trafficking, brokering, exportation, importation or possession of counterfeit medicines is guilty of an offence.

(2) In this section, "counterfeit medicine" means a medicine that is deliberately and fraudulently mislabelled with respect to its identity, source or both, whether it is a branded product or a generic product; and may include products with correct ingredients or with incorrect ingredients, without active ingredients, with insufficient active ingredients or with false packaging.

**Protection of purchasers of medicinal products**

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

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

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

(4) Subsection (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 sold or supplied in pursuance of a prescription given by a practitioner, subsections (1) to (4) shall have effect as if —

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

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

**Compliance with standards specified in monographs in certain publications**

**35.** (1) No person shall —

*(a)* sell a medicinal product which has been requested by the purchaser or by express reference to a particular name; or

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

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

(2) No person shall sell or supply a medicinal product by or by express reference to a particular name, if that name is a name at the head of the relevant monograph unless the product complies with the standard specified in that monograph.

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

(4) In this section "publication" means, the *British Pharmacopeia*, the *European Pharmacopeia*, *United States Pharmacopeia*, the *British Pharmaceutical Code*x or the *British Veterinary Codex*; and "relevant monograph", in relation to the sale or supply of a medicinal product by or by express reference to a particular name —

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

*(b)* if, together with the name, there was specified a particular publication, but not a particular edition of that publication, means the monograph 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 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,

and "current" means current at the time when the medicinal product in question is sold or supplied.

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

*(a)* the monograph headed by that name in the current edition of the *British Pharmacopoeia*, the E*uropean Pharmacopoeia* or the *United States Pharmacopoeia*;

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

*(c)* if there is no such monograph as in paragraphs *(a)* and *(b)*, then the monograph supplied by the manufacturer that has been approved during medicinal product registration.

(6) For the purposes of this section, an edition of a publication —

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

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

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

(7) The Minister may, with the approval of His Majesty the Sultan and Yang Di-Pertuan and by order published in the *Gazette* amend subsections (4), (5) and (6).

**Further powers to regulate sale and other dealings of medicinal products**

**36.** (1) The Minister may, with the approval of His Majesty the Sultan and Yang Di-Pertuan, make rules prescribing such requirements as he may consider necessary or expedient with respect to —

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

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

(2) Without prejudice to the generality of subsection (1), such rules may prescribe requirements in respect of —

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

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

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

**Offences under this Part**

**37.** (1) Any person who contravenes section 25, 27, 30, 32, 33, 34 or 35 or who contravenes any order made under section 29 is guilty of an offence.

(2) Where a medicinal product is sold, supplied or imported in contravention of an order made under section 31, any person who, otherwise than for the purpose of performing or exercising a duty or power imposed or conferred by or under this Act or any other written law, is in possession of the medicinal product, knowing or having reasonable cause to suspect that it was sold, supplied or imported in contravention of the order, is guilty of an offence.

(3) Any person guilty of an offence under subsection (1) or (2) is liable on conviction to a fine not exceeding $5,000, imprisonment for a term not exceeding 2 years or both.

(4) Any person who contravenes any conditions applied for the purpose of section 26 is guilty of an offence and liable on conviction to a fine not exceeding $2,000.

## PART 6

## PHARMACIES

**General provisions**

**38.** The Minister may impose conditions and requirements to be complied with by a person carrying on a retail pharmacy business.

**Registration of premises**

**39.** (1) The Authority shall keep a register of pharmacies for the purposes of this Part (referred to in this Part as the register) and, subject to the following provisions of this section shall, on payment of the prescribed fee, enter in the register any premises in respect of which an application is made under this section.

(2) An application for the registration of any premises under this section shall be made in the manner directed by the Authority and shall specify the premises to which the application relates and shall contain such other particulars as the Authority may require.

(3) If it appears to the Authority that in a material respect the premises do not comply with the requirements of the rules made under section 36 or that the applicant is not a suitable person to conduct a retail pharmacy business, it may refuse to register the premises.

(4) The applicant may appeal against the decision of the Authority to the Minister, whose decision is final.

**Supplementary provisions as to registration of premises**

**40.** (1) Where any premises have been entered in the register, then, in respect of each year subsequent to the year in which the premises were so entered, a further fee (referred to in this section as a retention fee) of the prescribed amount shall be payable by the person carrying on the retail pharmacy business at those premises.

(2) If the person carrying on a retail pharmacy business at any premises entered in the register fails to pay the retention fee in respect of those premises within one month from the date on which it is payable, the Authority may remove the premises from the register; but if, before the end of the year in respect of which the retention fee is payable or such longer period as in any particular case it may allow, the person carrying on the business pays to the Authority the retention fee in respect of that year, together with such additional sum (if any) by way of penalty as may be prescribed, the Authority may restore the premises to the register with effect from such date as it thinks fit.

(3) Where a change occurs in the ownership of a retail pharmacy business carried on at any premises registered under this Part, the registration of the premises shall become void at the end of 6 months from the date on which the change occurs.

(4) Where the registration of any premises under this Part in respect of a business becomes void by virtue of subsection (3), an application for the premises to be restored to the register may be made by the person who, in consequence of the change of ownership has become the owner of the business; and where such an application is made the Authority may restore the premises to the register.

(5) A certificate signed by the Authority 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.

**Restriction on use of titles, descriptions and emblems**

**41.** (1) No person shall —

*(a)* in connection with the retail sale of any medicinal products or the supply of any medicinal products in circumstances corresponding to retail sale, use the description "pharmacy" or "dispensary" except in respect of a registered pharmacy or in respect of the pharmaceutical department of a hospital under the supervision of a pharmacist;

*(b)* take or use the titles of chemist and druggist, druggist, dispensing chemist, dispensing druggist, pharmaceutical chemist, pharmaceutist and pharmacist, in connection with the retail sale of any medicinal products or the supply of any medicinal products in circumstances corresponding to retail sale at any premises unless those premises are a registered pharmacy or the pharmaceutical department of a hospital under the supervision of a pharmacist;

*(c)* in connection with any premises used for the purpose of the retail sale of medicinal products, use any title, description or emblem likely to suggest —

(i) that he possesses any qualification which he does not possess with respect to the sale, manufacture or assembly of medicinal products; or

(ii) that any person employed in those premises possesses any qualification which that person does not possess.

(2) Subsection (1) does not apply to the use of the word "dispensary" by a medical practitioner or veterinary surgeon in connection with the practice of his profession.

**Minister may modify restrictions under section 41**

**42.** The Minister may, with the approval of His Majesty the Sultan and Yang Di-Pertuan, by order modify any of the restrictions imposed by section 41.

**Power of Authority to disqualify and direct removal from register**

**43.** (1) Where a person carries on a retail pharmacy business and that person is convicted of an offence under any relevant written law, the

Authority may remove from the register all premises entered in the register as being premises at which that person carries on a retail pharmacy business.

(2) In this section "relevant written law" means this Act, the Poisons Act (Chapter 114), the Pharmacists Registration Order, 2001 (S 21/2001), the Misuse of Drugs Act (Chapter 27) and any subsidiary legislation respectively made thereunder.

**Appeal relating to disqualification**

**44.** Any person aggrieved by the decision of the Authority under section 43 may appeal to the Minister, whose decision is final.

**Offences under this Part**

**45.** Any person who contravenes section 41 is guilty of an offence and liable on conviction to a fine not exceeding $2,000.

## PART 7

## CONTAINERS, PACKAGES AND IDENTIFICATION OF MEDICINAL PRODUCTS

**Labelling and marking of containers and packages**

**46.** (1) The Minister may, with the approval of His Majesty the Sultan and Yang Di-Pertuan, make rules imposing such requirements as he considers necessary or expedient with respect to —

*(a)* the labelling of containers of medicinal products;

*(b)* the labelling of packages of medicinal products;

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

(2) No person shall sell or supply any medicinal product in such circumstances as to contravene any requirements imposed by such rules.

(3) In so far as any such requirements relate to the labelling or marking of containers of medicinal products, a person who sells or supplies a medicinal product to which the requirements are applicable without its being enclosed in a container shall, except in so far as the rules otherwise provide,

be taken to contravene those requirements as if he had sold or supplied it in a container not complying with those requirements.

(4) Without prejudice to subsections (1), (2) and (3), no person shall sell or supply any medicinal product in a container or package which is labelled or marked in such a way that the container or package —

*(a)* falsely describes that product; or

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

**Leaflets**

**47.** (1) The Minister may, with the approval of His Majesty the Sultan and Yang Di-Pertuan, make rules imposing such requirements as he considers necessary or expedient with respect to leaflets relating to medicinal products which are supplied, or which 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 supply with any medicinal product, or have in his possession for the purpose of so supplying, a leaflet which contravenes any requirements imposed by such rules.

(3) Without prejudice to subsections (1) and (2), no person shall supply with any medicinal product, or have in his possession for the purpose of so supplying, a leaflet which —

*(a)* falsely describes that product; or

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

**Requirements as to containers**

**48.** (1) The Minister may, with the approval of His Majesty the Sultan and Yang Di-Pertuan, make rules prohibiting the sale or supply of medicinal products otherwise than in containers which comply with such requirements as the Minister considers necessary or expedient, and in particular requiring 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 sell or supply, or have in his possession for the purpose of sale or supply, any medicinal product in such circumstances as to contravene any requirements imposed by such rules.

**Distinctive colours, shapes and markings of medicinal products**

**49.** (1) The Minister may, with the approval of His Majesty the Sultan and Yang Di-Pertuan, make rules imposing such requirements as he considers necessary or expedient with respect to —

*(a)* the colour of medicinal products;

*(b)* the shape of medicinal products; and

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

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

(3) No person shall sell or supply, or have in his possession for the purpose of sale or supply, any medicinal product which contravenes any requirements imposed by such rules.

**Offences under this Part**

**50.** Any person who contravenes section 46(2), (3) or (4), 47(2) or (3), 48(2) or 49(3) is guilty of an offence and liable on conviction to a fine not exceeding $5,000, imprisonment for a term not exceeding 2 years or both.

## PART 8

## PROMOTION OF SALES OF MEDICINAL PRODUCTS AND MEDICAL ADVERTISEMENTS

**Interpretation of this Part**

**51.** (1) In this Part —

"advertisement" subject to subsection (2), includes every form of advertising, whether in a publication, or by the display of any

notice or sign board, or by means of any catalogue, price list, letter (whether circular or addressed to a particular person) or other documents, or by words inscribed on any article, or by the exhibition of a photograph or cinematograph film, or by way of sound recording, sound broadcasting or television or internet or any forms of electronic transmission, or in any other way but does not include spoken words unless they are —

*(a)* words forming part of a sound recording or embodied in a soundtrack associated with a cinematograph film; or

*(b)* words broadcast by way of sound broadcasting or television or transmitted to subscribers to a diffusion service;

"medical advertisement" means an advertisement relating or likely to cause any person to believe that it relates to any medicinal product or any device, instrument, apparatus or contrivance used or represented to be used for a medicinal purpose;

"representation" means any statement or undertaking (whether constituting a condition or a warranty or not) which consists of spoken words falling within paragraph *(a)* or *(b)* of the definition of "advertisement".

(2) Except as provided by section 54, for the purposes of this Part neither of the following shall be taken to constitute the issue of an advertisement —

*(a)* the 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.

**False or misleading advertisements and representations**

**52.** (1) Subject to the following provisions of this section, any person who issues or causes another person to issue a false or misleading advertisement relating to medicinal products of any description is guilty of an offence.

(2) Where a 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 the medicinal products of that description may be recommended to be used are limited to those specified in the licence, then, subject to the following provisions of this section, any person who issues or causes another person to issue an advertisement relating to medicinal products of that description which consists of or includes an unauthorised recommendation is guilty of an offence.

(3) Subject to the following provisions of this section, any person who makes a false or misleading representation relating to a medicinal product in connection with the sale of that product is guilty of an offence; and any person who makes a false or misleading representation relating to medicinal products of a particular description —

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

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

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

is guilty of an offence.

(4) Where, in the circumstances specified in subsection (2), any person who —

*(a)* in connection with the sale of a medicinal product of the description in question, makes a representation relating to that product which consists of or includes unauthorised recommendations; or

*(b)* for any such purpose specified in subsection (3)*(a)*, *(b)* and *(c)*, makes a representation relating to medicinal products of that description which consists of or includes unauthorised recommendations,

is subject to the following provisions of this section, guilty of an offence.

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

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

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

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

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

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

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

(7) Any person guilty of an offence under this section is liable on conviction to a fine not exceeding $5,000, imprisonment for a term not exceeding 2 years or both.

(8) In this section —

*(a)* "false or misleading advertisement" includes an advertisement which is not consistent with the information regarding a medicinal product that was approved during the medicinal product registration process under section 11;

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

**Prohibition of certain medical advertisements**

**53.** (1) No person shall publish or cause to be published —

*(a)* any medical advertisement which directly or indirectly claims, indicates or suggests that the article advertised will prevent, alleviate or cure any disease or condition specified in the Schedule; or

*(b)* any advertisement referring to any skill or service relating to the treatment of any disease or condition affecting the human body.

(2) Subsection (1) does not apply to any advertisement which is distributed only to, or is contained in a publication intended for circulation mainly among one or more of the following classes of persons —

*(a)* medical practitioners;

*(b)* dentists;

*(c)* pharmacists;

*(d)* nurses;

*(e)* midwives;

*(f)* veterinary surgeons;

*(g)* persons undergoing training with a view to becoming medical practitioners, dentists, pharmacists, nurses, midwives or veterinary surgeons.

(3) Any person who contravenes subsection (1) is guilty of an offence and liable on conviction to a fine not exceeding $5,000, imprisonment for a term not exceeding 2 years or both.

(4) The Minister may by order published in the *Gazette* exempt any advertisement or class of advertisement from subsection (1).

**Power to regulate advertisements and representations**

**54.** (1) The Minister may by order prohibit —

*(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 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 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 effect of the products or as to any condition of body or mind in connection with which those products might be used.

(2) Without prejudice to subsection (1), the Minister may by order impose such requirements as he considers necessary or expedient with respect to —

*(a)* the form and content of advertisements relating to medicinal products;

*(b)* the obtaining of prior approval from the Authority for the issue of any such advertisements;

*(c)* in the case of advertisements by way of cinematograph films or television, or internet or any form of electronic transmission, 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;

*(d)* advertisements and representations directed to practitioners,

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.

**Power of Authority to require copies of advertisements**

**55.** (1) The Authority may serve on any person a notice requiring him, within such time as may be specified in the notice, to furnish to the Authority such number of copies as may be so specified of any advertisement relating to medicinal products or to medicinal products of a description or falling within a class so specified, which that person has issued, or has caused to be issued, within one year ending with the date of service of the notice.

(2) Any person who without reasonable excuse fails to comply with any requirement imposed on him by a notice under this section is guilty of an offence and liable on conviction to a fine not exceeding $2,000.

## PART 9

## MISCELLANEOUS AND SUPPLEMENTARY PROVISIONS

**Application of Act to certain articles and substances**

**56.** The Minister may by order published in the *Gazette* specify any description or class of articles or substances appearing to him to be articles or substances which are not medicinal products but which are manufactured, sold, supplied, imported or exported for use wholly or partly for a medicinal purpose or as a cosmetic product, and may by that order direct that, subject to such exceptions and modifications as may be specified in the order, such provisions of this Act as may be so specified (including any provisions so specified which relate to offences or penalties) shall have effect in relation to articles or substances of that description or class as those provisions have effect in relation to medicinal products.

**Application of Act to certain other substances not medicinal products**

**57.** The Minister may by order published in the *Gazette* specify any substance appearing to him to be a substance which is not itself a medicinal product but which —

*(a)* is used as an ingredient in the manufacture of medicinal products; or

*(b)* if used without proper safeguard, 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 Act as may be so specified (including any provisions so specified which relate to offences or penalties) shall have effect in relation to that substance as those provisions have effect in relation to medicinal products.

**Appointment of officers and inspectors**

**58.** (1) The Minister may appoint such number of officers and inspectors as he considers are necessary for the purposes of this Act.

(2) The Minister may give directions with respect to the conduct of the duties of officers and inspectors under this Act.

(3) The officers and inspectors appointed under subsection (1) are deemed to be public servants within the meaning of the Penal Code (Chapter 22).

**Rights of entry**

**59.** (1) Any person duly authorised in writing by the Authority may at any reasonable time —

*(a)* enter any premises for the purpose of ascertaining whether there is or has been, on or in connection with those premises, any contravention of this Act or under any rules or orders made thereunder;

*(b)* enter any premises for the purposes of the performances by the Authority of its functions under this Act or under any rules or orders made thereunder; or

*(c)* enter any ship, vessel, aircraft, hovercraft or vehicle for the purpose of ascertaining whether there is in that ship, vessel, aircraft, hovercraft or vehicle any substance or article imported in contravention of this Act or of any rules or orders made thereunder.

(2) Without prejudice to subsection (1), any person duly authorised in writing by the Authority may at any reasonable time enter any premises occupied by an applicant for a licence or certificate or for renewal thereof for the purpose of verifying any statement contained in the application for the licence or certificate.

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

**60.** (1) For the purpose of ascertaining whether there is or has been a contravention of this Act or of any rules or orders made thereunder, any person duly authorised in writing by the Authority may inspect —

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

*(b)* any article appearing to him to be a container or package used or intended to be used to contain any medicinal product or to be a label or leaflet used or intended to be used in connection with a medicinal product; or

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

(2) Where for any purpose specified in subsection (1) an authorised person requires a sample of any substance or article appearing to him to be —

*(a)* a medicinal product sold or supplied or intended to be sold or supplied; or

*(b)* a substance or article used or intended to be used in the manufacture of a medicinal product,

he may take a sample of that substance or article.

(3) For any purpose specified in subsection (1), an authorised person may —

*(a)* 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 that business which are in his possession or under his control; and

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

(4) An authorised person may seize and detain any substance or article (including any document) which he has reasonable cause to believe to be a substance or article in relation to which, or by means of which, an offence under this Act is being or has been committed, and any document which he has reasonable cause to believe to be a document which may be required as evidence in proceedings under this Act.

(5) An authorised person may, so far as is reasonably necessary in order to ensure that the provisions of this Act and of any rules or orders made thereunder are duly observed, require any person having authority to do so to break open any container or package or to open any vending machine, or to permit him to do so.

(6) Where an authorised person seizes any substance or article under subsection (4), he shall inform the person from whom it is seized, and in the case of 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) The Minister may give directions with respect to the procedure for the sampling of articles and substances seized under this section.

**Supplementary provisions as to rights of entry and related rights**

**61.** (1) Any person entering any premises or any other place by virtue of section 59 may take with him such other persons and such equipment as may appear to him to be necessary.

(2) Any person who —

*(a)* wilfully obstructs any person acting in pursuance of this Act who is duly authorised so to act by the Authority;

*(b)* wilfully fails to comply with any requirement properly made to him by any person acting under section 60; or

*(c)* without reasonable cause, fails to give to any such person such assistance or information which that person may reasonably

require of him for the purpose of the performance of his functions under this Act,

is guilty of an offence and liable on conviction to a fine not exceeding $2,000.

(3) Any person who, in giving any such information mentioned in subsection (2)*(c)*, makes any statement which he knows to be false, is guilty of an offence and liable on conviction to a fine not exceeding $5,000, imprisonment for a term not exceeding 2 years or both.

**Seizure or detention of goods subject to prohibition or restriction**

**62.** (1) Any imported goods are deemed to be imported contrary to a prohibition or restriction with respect to them if —

*(a)* they are medicinal products or medicinal substances of any description or falling within a class specified in an order made by the Minister for the purpose of this section; and

*(b)* they are imported in such circumstances as are specified in that order.

(2) Any exported goods are deemed to be exported contrary to a prohibition or restriction with respect to them if —

*(a)* they are medicinal products or medicinal substances of any description or falling within a class specified in an order made by the Minister for the purpose of this section; and

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

(3) An officer of customs (as defined in section 2(1) of the Customs Order, 2006 (S 39/2006) or a police officer may seize and detain any goods subject to a prohibition or restriction imposed by an order made under this section.

**Forfeiture of goods seized**

**63.** (1) Whenever any goods are seized under this Act, the seizing officer shall forthwith give notice in writing of the seizure to the owner of the goods,

if known, either by delivering the notice to him personally or by post at his place of abode if known:

Provided that the notice shall not be required to be given where the seizure is made in the presence of the offender or the owner or his agent, or in the case of a ship, vessel, aircraft or hovercraft, in the presence of the master or captain thereof.

(2) An order for the forfeiture of any goods may be made if it is proved to the satisfaction of the court that an offence against this Act has been committed and that the goods were the subject matter of or were used in the commission of the offence, notwithstanding that no person may have been convicted of that offence.

(3) If there is no prosecution with regard to any goods seized under this Act, the goods shall be forfeited at the expiration of one month from the date of the seizure thereof unless a claim thereto has been made before that date.

**Disposal of goods forfeited**

**64.** (1) All goods which are forfeited under this Act shall be disposed of in such manner as the Minister may direct.

(2) The Minister may, after any proceedings under this Act are concluded, entertain and give effect to any claim to or in respect of goods which have been forfeited.

**Restrictions on disclosure of information**

**65.** (1) Any person who discloses to any other person —

*(a)* any information with respect to any manufacturing process or trade secret obtained by him in premises which he has entered by virtue of section 59; or

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

is, unless the disclosure was made in the performance of his duty, guilty of an offence.

(2) Any person guilty of an offence under this section is liable on conviction to a fine not exceeding $5,000, imprisonment for a term not exceeding 2 years or both.

**Protection of officers**

**66.** No person shall be personally liable in respect of any act done by him in the execution or purported execution of this Act and within the scope of his authority if he did it in the honest belief that his duty under this Act required or entitled him to do it.

**Contravention due to default of another person**

**67.** (1) Where a contravention by any person of any provision to which this section applies constitutes an offence under this Act, and is due to an act or default of another person, then whether proceedings are taken against the first-mentioned person or not, that other person may be charged with and convicted of that offence and be liable on conviction to the same punishment as might have been imposed on the first-mentioned person if he had convicted of that offence.

(2) Where a person who is charged with an offence under this Act in respect of contravention of a provision to which this section applies proves to the satisfaction of the court —

*(a)* that he exercised all due diligence to secure that that provision 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 section applies to sections 32 to 35, 46 to 49 and 52 to 54 and to the provisions of any rules made under any of those sections.

**Warranty as defence**

**68.** (1) Subject to the following provisions of this section, in any proceedings for an offence under this Act in respect of a contravention of a provision to which this section applies, it shall be a defence for the accused to prove —

*(a)* that he purchased the substance or article to which the contravention relates in Brunei Darussalam as being a substance or article which could be lawfully sold or supplied or could be lawfully sold or supplied under the name or description or for the purpose under or for which he sold or supplied and with written warranty to that effect;

*(b)* that at the time of the commission of the alleged offence he had no reason to believe that it was otherwise; and

*(c)* that the substance or article was then in the same state as when he purchased it.

(2) This section applies to sections 32*(b)*, 34, 35 and 46 to 49 and to the provisions of any rules made under any of those sections.

(3) A warranty shall not be a defence by virtue of this section unless the defendant has, not later than 7 clear days before the date of hearing —

*(a)* sent to the prosecution a copy of the warranty with a notice stating that he intends to rely on it and specifying the name and address of the person from whom he received it; and

*(b)* sent a like notice to that person.

(4) Where the accused is an employee of the person who purchased the substance or article under the warranty, he shall be entitled to rely on this section in the same way as his employer would have been entitled to do if he had been charged with the offence.

(5) The person by whom the warranty is alleged to have been given shall be entitled to appear at the hearing and to give evidence, and the court may adjourn the hearing to enable him to do so.

(6) For the purposes of this section, a name or description entered in an invoice is deemed to be a written warranty that the article or substance to which the name or description applies can be sold or supplied under that name or description by any person without contravening any provision to which this section applies.

**Offences in relation to warranties**

**69.** (1) If an accused in any such proceedings as are mentioned in section 68(1) wilfully applies to any substance or article a warranty given in relation to a different substance or article he is guilty of an offence.

(2) Any person who, in respect of any substance or article sold by him in respect of which a warranty might be pleaded under section 68, gives to the purchaser a false warranty in writing is guilty of an offence, unless he proves that when he gave the warranty he had reason to believe that the statement or description contained in it was accurate.

(3) Any person guilty of an offence under this section is liable on conviction to a fine not exceeding $5,000, imprisonment for a term not exceeding 2 years or both.

**Offences by bodies corporate**

**70.** (1) Where an offence under this Act which has been 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 that body or of any person who was purporting to act in any such capacity, he, as well as the body corporate, is also guilty of that offence and liable to be proceeded against and punished accordingly.

(2) In relation to a body corporate carrying on a retail pharmacy business, subsection (1) shall have effect in relation to any person who (not being such an officer of the body corporate as is mentioned therein) —

*(a)* is the superintendent; or

*(b)* at any premises where the business is carried on, is the pharmacist who acts under the directions of the superintendent,

as if he were also such an officer of that body corporate.

**Certificate of analysis**

**71.** In any proceedings under this Act, a certificate of analysis purporting to be signed by an analyst appointed by the Authority shall, on its production by the prosecution without proof of the signature of that analyst, be sufficient evidence of the facts stated therein until the contrary is proved.

**Presumptions**

**72.** (1) For the purposes of any proceedings under this Act for an offence consisting of —

*(a)* offering a medicinal product for sale by retail in contravention of section 25 or of any conditions prescribed for the purpose of section 26; or

*(b)* offering a medicinal product for sale in contravention of section 32*(b)*,

where it is proved that that medicinal product was found on a vehicle or stall from which medicinal products are sold, it shall be presumed, until the contrary is proved, that the person in charge of that vehicle or stall offered that medicinal product for sale and, in a case falling within paragraph *(a)*, that he offered it for sale by retail.

(2) For the purposes of any proceedings under this Act for an offence consisting of a contravention of so much of any provision to which this subsection applies as relates to a person having any medicinal product in his possession for the purpose of sale or supply, where it is proved that the medicinal product in question was found in any premises occupied by the person charged with the offence or under his control, it shall be presumed, until the contrary is proved, that he had that medicinal product in his possession for the purpose of sale or supply.

(3) Subsection (2) applies to sections 32*(b)*, 33, 46(2) and (4), 48(2) and 49(3).

(4) For the purposes of any proceedings under this Act for an offence consisting of a contravention of section 47(2) or (3), in relation to leaflets, where it is proved that the leaflet in question was found in any premises occupied by the person charged with the offence or under his control, it shall be presumed, until the contrary is proved, that he had the leaflet in his possession for the purpose of supplying it with a medicinal product.

**Service of documents**

**73.** Any notice or other document required or authorised by this Act to be served on any person, or to be given or sent to any person, may be served, given or sent —

*(a)* by delivering it to him;

*(b)* by sending it by post to him at his usual or last-known residence or place of business in Brunei Darussalam; or

*(c)* in the case of a body corporate, by delivering it to the secretary of the body corporate at its registered or principal office or by sending it by post to the secretary of that body corporate at that office.

**Reporting adverse reactions**

**74.** A licensed manufacturer, a licensed wholesaler, a licensed importer or the holder of a product licence in respect of any product shall notify the Authority of any adverse reactions arising from the use of the registered medicinal product immediately after he receives notice of such adverse reactions.

**Directions**

**75.** (1) The Authority may issue such directions to any person as it thinks necessary for the better carrying out of the provisions of this Act, which may in particular relate to the recall of any registered medicinal product from the market and the disposal of any registered medicinal product.

(2) Any person who contravenes any directions issued by the Authority under subsection (1) is guilty of an offence.

**Power to grant exemption**

**76.** The Minister may, after consultation with the Authority and by notification published in the *Gazette*, exempt, either permanently or for such period as he may determine any person or class of person from any of the provisions of this Act subject to such conditions or restrictions as he may impose.

**Compounding of offences**

**77.** The Authority may compound any offence against this Act or under any rules made thereunder by collecting from the person reasonably suspected of having committed the offence a sum not exceeding $2,000.

**Penalty for offences not otherwise provided for**

**78.** Any person who commits any offence against this Act for which no penalty is provided is liable on conviction to a fine not exceeding $1,000.

**Advisory committees**

**79.** The Minister may establish one or more advisory committees consisting of such members as he may appoint for the purpose of giving advice to the Authority with regard to such matters arising out of the administration of this Act as are referred to them by him.

**Amendment of Schedule**

**80.** The Minister may, with the approval of His Majesty the Sultan and Yang Di-Pertuan, by notification published in the *Gazette*, amend the Schedule.

**Regulations**

**81.** (1) The Minister may, with the approval of His Majesty the Sultan and Yang Di-Pertuan, make regulations which are necessary or expedient for giving effect to and carrying out the provisions of this Act, including the prescription of fees and of any other thing required to be or which may be prescribed under this Act, and for the due administration thereof.

(2) Such regulations may apply to articles or substances which are not medicinal products but which are manufactured, sold, supplied, imported or exported for use wholly or partly for a medicinal purpose or as a cosmetic product.

(3) Such regulations may include such incidental, consequential and supplementary provisions as the Minister considers necessary or expedient.

(4) Such regulations may provide that any contravention thereof shall be punishable with a fine not exceeding $5,000, imprisonment for a term not exceeding 2 years or both.

**Application of other written laws not affected**

**82.** Except as expressly provided in this Act, nothing in this Act shall limit or affect the provisions or operation of any other written law relating to any matter dealt with by this Act.

## SCHEDULE

(sections 53(1)*(a)* and 80)

DISEASES OR CONDITIONS

1. Acquired Immunodeficiency Syndrome (AIDS)
2. Asthma
3. Cancer
4. Conception and pregnancy
5. Deafness
6. Diabetes
7. Diseases of the eye
8. Diseases or defects of the heart
9. Diseases or defects of the kidney
10. Drug addiction
11. Epilepsy or fits
12. Frigidity
13. Hernia or rupture
14. Hypertension
15. Impairment of the sexual function or impotency
16. Infertility
17. Leprosy
18. Mental disorder
19. Paralysis
20. Sexual function
21. Tuberculosis
22. Venereal disease.