THE STATUTES OF THE REPUBLIC OF SINGAPORE

MEDICINES ACT 1975

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Medicines Act 1975

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An Act to make provisions with respect to medicinal products and medical advertisements and matters connected therewith; and to make consequential amendments to the Poisons Act 1938.

[24 June 1977: Parts I and II, sections 30, 31, 34, and 35 of Part III, Part V and sections 54 to 75 of Part VII ; 15 November 1977: Part VI ; 16 January 1981: Part IV ; 3 May 1993: Part III except sections 30, 31, 34 and 35]

PART 1

PRELIMINARY

Short title and commencement

1.—(1) This Act is the Medicines Act 1975.

(2) Section 76 and the Second Schedule come into operation on a date that the Minister appoints by notification in the *Gazette*.

[S 759/2022]

General 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 and "analyse" has a corresponding meaning;

"analyst" means an analyst appointed by the licensing authority;

"animal" includes any bird, fish or reptile;

"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;

"Authority" means the Health Sciences Authority established under the Health Sciences Authority Act 2001;

"Chief Executive of the Authority" means the person appointed under section 15 of the Health Sciences Authority Act 2001 to be the Chief Executive of the Authority;

"clinical trial" means an investigation or series of investigations consisting of the administration of one or more medicinal products of a particular description by, or under the direction of —

(*a*) a doctor or dentist to one or more of his or her patients; or

(*b*) two 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 of his or her patients,

where (in any such case) there is evidence that medicinal products of that description have effects which may be beneficial to the patient or patients 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;

"composition", in relation to a medicinal product, means the ingredients of which it consists and the proportions, and the

degrees of strength, quality and purity, in which those ingredients are contained in it respectively;

"container", in relation to a medicinal product, means the bottle, jar, box, packet or other receptacle which contains or is to contain it, not being a capsule, cachet, or other article in which the product is or is to be administered, and where any such receptacle is or is to be contained in another such receptacle, includes the former but does not include the latter receptacle;

"contravention" includes failure to comply and "contravene" has a corresponding meaning;

"dentist" means a person registered under the Dental Registration Act 1999 whose name appears in the first division of the Register of Dentists;

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

"doctor" means a person registered under the Medical Registration Act 1997;

"herbal remedy" means a medicinal product consisting of a substance produced by subjecting a plant or plants to drying, crushing or other process or of a mixture whose ingredients are 2 or more substances so produced, or of a combination of such mixture with water or such other inert substances as the licensing authority may, by notification in the *Gazette*, specify;

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

"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;

"licensing authority" means the appropriate licensing authority as defined in section 4(1);

"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;

"medicinal test on animals" means an investigation or series of investigations consisting of any of the following:

(*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 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 or whether there is evidence that it has effects which may be beneficial

to, or otherwise advantageous in relation to, that animal or those animals;

"midwife" means a registered midwife within the meaning of the Nurses and Midwives Act 1999;

"Minister" means —

(*a*) except as provided in paragraph (*b*), the Minister for Health; and

(*b*) for the purpose of performing any function under this Act (whether by the making of any regulations or order or otherwise) where the function is performed exclusively in relation to veterinary medicinal products and animals, the Minister for National Development;

"nurse" means a registered nurse or enrolled nurse within the meaning of the Nurses and Midwives Act 1999;

"package", in relation to any medicinal product, 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 boxes, packets or other articles, includes each of the boxes, packets or articles in question;

"pharmacist" means a person who is registered as a pharmacist under the Pharmacists Registration Act 2007 and has in force a valid practising certificate issued under that Act;

"plant" includes any part of a plant;

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

"product licence", "manufacturer's licence" and "wholesale dealer's licence" have the meanings given by sections 5 and 6 and include any such provisional licence;

"retail sale", in relation to a medicinal product, has the meaning given by subsection (2);

"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, and "sale" and "sold" have corresponding meanings;

"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;

"veterinary medicinal products" means medicinal products which are 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 who holds a veterinary qualification approved by the Minister and who is licensed to treat, vaccinate or inoculate animals or birds under section 53(1) of the Animals and Birds Act 1965;

"wholesale dealing", in relation to a medicinal product, has the meaning given by subsection (2).

[46/99; 4/2001; 22/2007; 48/2007; 4/2021]

(2) In this Act any reference to —

(*a*) selling anything by way of wholesale dealing is a reference to selling it to a person as being 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.

Meaning of "medicinal product" and related expressions

3.—(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 of terminating, reducing or postponing, or increasing or accelerating, the operation of that function or in any other way.

(3) Despite 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 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 paragraphs (*a*), (*b*) and (*c*).

(4) In this Act, "medicinal product" also 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; and

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

(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 does not cease to be a medicinal product for the purposes of this Act by reason only that, at any subsequent time, it is sold, supplied, imported or exported for use wholly or mainly in a way other than those specified in 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; and

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

and in this Act "description", in relation to medicinal products, is to be construed accordingly.

(7) For the purposes of this Act a document, advertisement or representation is to 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:

(*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;

(*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

LICENCES AND CERTIFICATES RELATING TO MEDICINAL PRODUCTS

Licensing authority

4.—(1) For the purposes of this Part, the authority responsible for the grant, renewal, variation, suspension and revocation of licences and certificates is —

(*a*) except as provided in paragraph (*b*), the Chief Executive of the Authority; and

(*b*) the Director-General, Animal Health and Welfare appointed under section 3(1) of the Animals and Birds Act 1965 in respect of any function to be performed under this Act exclusively in relation to veterinary medicinal products and animals.

[4/2001; 10/2019]

(2) Any function conferred on the licensing authority by this Act may be performed by such officers as the licensing authority may designate, subject to the licensing authority's general direction and control.

(3) Any person to whom a licensing authority refuses to grant, renew or vary a licence or whose licence has been suspended or revoked may appeal to the Minister whose decision is final.

General provisions as to dealing with medicinal products

5.—(1) Except in accordance with a licence granted for the purposes of this section (called in this Act a product licence) a person must not in circumstances to which this section applies —

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

(*b*) procure the sale, supply or export of any medicinal product; or

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

(2) A person must not import any medicinal product except in accordance with a product licence or an import licence.

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

(4) In relation to any medicinal product which has not been imported, this section applies to any circumstances in which the person selling, supplying or exporting the medicinal product in question, or procuring the sale, supply or export or the manufacture or assembly for sale, supply or export of that product, is responsible for the composition of the product.

(5) For the purposes of subsection (4), a person is taken to be responsible for the composition of a medicinal product if —

(*a*) the person procures the manufacture of the product to the person's 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 pursuant to an order which fulfils the conditions specified in paragraph (*a*).

Provisions as to manufacture and wholesale dealing

6.—(1) This section has effect without affecting section 5.

(2) A person must not manufacture or assemble any medicinal product except in accordance with a licence granted for the purposes of this subsection (called in this Act a manufacturer's licence).

(3) A person must not sell any medicinal product by way of wholesale dealing except in accordance with a licence granted for the purposes of this subsection (called in this Act a wholesale dealer's licence).

(4) A manufacturer's licence does not have effect so as to authorise the manufacture or assembly of medicinal products of any description for sale or supply to any other person, or for export, unless —

(*a*) the holder of the licence is also the holder of a product licence which is applicable to medicinal products of that description; or

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

and the products are manufactured or assembled in accordance with that product licence.

Exemptions for pharmacists and practitioners

7.—(1) The restrictions imposed by sections 5 and 6 do not apply to anything which is done in a hospital by or under the supervision of a pharmacist —

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

(*b*) in assembling a medicinal product; or

(*c*) in procuring the preparation or dispensing of a medicinal product in accordance with a prescription given by a

practitioner, or in procuring the assembly of a medicinal product.

[4/2021]

(2) Without affecting subsection (1), the restrictions imposed by sections 5 and 6 do not apply to anything which is done in a hospital by or under the supervision of a pharmacist —

(*a*) in 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 pursuant to which that product is prepared or dispensed; or

(*b*) in preparing a stock of medicinal products with a view to dispensing them as mentioned in subsection (1)(*a*) or in paragraph (*a*).

[4/2021]

(3) The restrictions imposed by sections 5 and 6 do not apply to the preparation, dispensing and assembly of any medicinal product by or under the supervision of a practitioner for the purpose of administration to a patient or animal under the practitioner's care.

(4) The exemptions conferred by subsections (1), (2) and (3) do not apply to veterinary biologics except where such veterinary biologics are prepared in a veterinary centre.

[4/2021]

(5) For the purpose of subsection (4) —

"veterinary biologics" means aggressions, serums, viruses, toxins, tuberculin, mallein, Johnin, abortin, vaccines, micro-organisms either living or killed, and products of micro-organisms intended for use in the treatment or diagnosis of diseases of animals and birds;

"veterinary centre" means a veterinary centre established under section 54 of the Animals and Birds Act 1965.

Exemption in respect of herbal remedies

8.—(1) The restrictions imposed by sections 5 and 6 do not apply to the import, sale, supply, manufacture or assembly of any herbal remedy where —

(*a*) the remedy is manufactured or assembled on premises of which the person carrying on the business is the occupier and which the person 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 that person's judgment as to the treatment required.

(2) Those restrictions also do not apply to the import, 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 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.

General exemptions

9. The Minister may by order —

(*a*) provide that, in relation to any medicinal product which was available for sale in Singapore immediately before 24 June 1977, sections 5 and 6 have effect only after the period specified in the order; and

(*b*) provide for any other exemptions from the restrictions imposed by sections 5 and 6 that the Minister thinks fit.

Register of medicinal products and import licence

10.—(1) The licensing authority must maintain a register in which must be entered all medicinal products in respect of which product licences have been granted and remain in force.

(2) The register must be in such form and contain such particulars as the licensing authority may determine.

(3) The licensing authority may, on application by a person who is not the holder of a product licence, grant an import licence to that person to import any medicinal product for sale or supply where the licensing authority is satisfied that that product is in all respects the same as a medicinal product registered under subsection (1).

Application for licence

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

(2) Any such application must 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.

Factors relevant to determination of application for licence

12.—(1) Subject to the following provisions of this Part, in dealing with an application for a product licence the licensing authority must 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;

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

(*d*) whether the grant of a product licence for the medicinal products to which the application relates will be in the public interest.

[15/2007]

(2) 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, insofar as it relates to those products, the licensing authority must also take into consideration in particular the methods, standards and conditions of manufacture of those products and may, if the licencing authority thinks fit, require the production by the applicant of any one or more of the following:

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

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

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

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

(*a*) the operations proposed to be carried out pursuant to 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 pursuant to the licence.

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

(*a*) the premises in 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 in those premises;

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

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

Whether medicinal product subject to patent

12A.—(1) Subject to the provisions of this Part, in dealing with an application for a product licence, the licensing authority must consider whether a patent under the Patents Act 1994 is in force in respect of any medicinal product to which the application relates and, if so —

(*a*) whether the applicant is the proprietor of the patent; or

(*b*) if the applicant is not the proprietor of the patent, whether —

(i) the proprietor has given consent to or has acquiesced in the grant of the licence to the applicant; or

(ii) the patent is invalid or will not be infringed by the doing of the act for which the licence is sought.

[26/2004]

(2) Unless the licensing authority otherwise determines, an applicant for a product licence must, at the time of the applicant's application and at such other time as the licensing authority may require, make and furnish to the licensing authority a declaration in the prescribed form —

(*a*) stating whether a patent under the Patents Act 1994 is in force in respect of any medicinal product to which the application relates;

(*b*) if the applicant states that there is such a patent, stating whether the applicant is the proprietor of the patent; and

(*c*) if the applicant states that the applicant is not the proprietor of the patent, stating —

(i) the name and other particulars of the proprietor of the patent;

(ii) whether —

(A) the proprietor has consented to or has acquiesced in the grant of the licence to the applicant; or

(B) in the applicant's opinion and to the best of the applicant's belief, the patent is invalid or will not be infringed by the doing of the act for which the licence is sought; and

(iii) any other information that may be prescribed.

[26/2004]

(3) The licensing authority may, if the applicant has declared that in the applicant's opinion and to the best of the applicant's belief the patent is invalid or will not be infringed by the doing of the act for which the licence is sought, or if the licensing authority considers it appropriate in any particular case, require the applicant to do the following within such time as the licensing authority may determine:

(*a*) serve on the proprietor of the patent a notice in the prescribed form of the applicant's application;

(*b*) furnish to the licensing authority such evidence of the service as the licensing authority may require.

[26/2004]

(4) The licensing authority need not determine the application until the applicant has complied with subsection (2) and, where applicable, subsection (3), to the reasonable satisfaction of the licensing authority.

[26/2004]

(5) If the licensing authority is satisfied that a notice mentioned in subsection (3)(*a*) has been served on the proprietor of the patent, the licensing authority may grant the licence to the applicant if the proprietor has not, before the expiry of the period prescribed for the purposes of this subsection —

(*a*) applied for the order or declaration by a court or the Registrar of Patents or a Deputy Registrar of Patents holding office under the Patents Act 1994, as specified in that notice; and

(*b*) given written notice to the licensing authority stating that such application has been made.

[26/2004]

(6) The licensing authority may grant the licence to the applicant if —

(*a*) application for the order or declaration mentioned in subsection (5)(*a*) has been made; and

(*b*) at the expiry of the period prescribed for the purposes of this subsection, the order or declaration has not been obtained.

[26/2004]

(7) For the purpose of subsection (1), the licensing authority may rely upon and must not be concerned to inquire into the truth of any statement made in a declaration furnished under subsection (2).

[26/2004]

(8) This section applies only to an application for a product licence made on or after 1 July 2004.

[26/2004]

Grant or refusal of licence

13. Subject to the provisions of this Act, on any application to the licensing authority for a licence under this Part the licensing authority —

(*a*) may grant a licence containing any provisions that the licensing authority considers appropriate; or

(*b*) if, having regard to the provisions of this Act, the licensing authority considers it necessary or expedient to do so, may refuse to grant a licence.

Duration and renewal of licence

14.—(1) Subject to the following provisions of this section, every licence granted under this Part, unless previously revoked, must be for the prescribed period.

(2) Any such licence, if it has not been revoked, may, on the application of the holder of the licence, be renewed by the licensing authority for the prescribed period or for such shorter period as the licensing authority may determine.

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

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

(*b*) may grant to the applicant a new licence containing any provisions that the licensing authority considers appropriate; or

(*c*) if, having regard to the provisions of this Act, the licensing authority considers it necessary or expedient to do so, may refuse to renew the licence or to grant a new licence.

(4) Where an application for the renewal of a licence under this Act has been duly made, the licence does not cease to be in force by virtue of subsections (1), (2) and (3) before the licensing authority has determined the application.

Provisional licences

15.—(1) The Minister may by regulations provide for the issue of provisional licences to such persons and on such terms as may be prescribed.

(2) Section 12 does not have effect in relation to applications for provisional licences.

General power to suspend, revoke or vary licences

16.—(1) Subject to subsection (5), the licensing authority may suspend a licence under this Part for the period that the Authority determines or may revoke, or vary the provisions of, any such licence.

(2) Without limiting subsection (1), the licensing authority may, upon the request of the holder of a licence, revoke the licence.

[26/2004]

(3) Without limiting subsection (1), the licensing authority may, upon an application by any interested person, revoke a product licence if the licensing authority is satisfied that —

(*a*) a court, or the Registrar of Patents or a Deputy Registrar of Patents holding office under the Patents Act 1994, has determined that the doing of an act authorised by the licence infringes a patent under the Patents Act 1994;

(*b*) the person who made a declaration mentioned in section 12A(2) in support of the application for the licence has been convicted for an offence under section 20 in respect of the declaration; or

(*c*) a court has determined that the declaration —

(i) contains a statement that is false or misleading in a material particular; or

(ii) omits to disclose any matter that is material to the application,

and the determination or conviction (as the case may be) is final.

[26/2004]

(4) The suspension or revocation of a licence under this section may be total or may be limited to medicinal products of one or more

descriptions or to medicinal products manufactured, assembled or stored in any particular premises or in a particular part of any premises.

(5) Where the licensing authority proposes to exercise any power conferred by this section, the licensing authority must serve on the holder of the licence a notice giving particulars of the suspension, revocation or variation and of the reasons for the licensing authority's decision to suspend, revoke or vary the licence.

(6) For the purposes of subsection (3), a determination or conviction is final if —

(*a*) it is upheld on appeal, review or revision;

(*b*) it is not subject to further appeal;

(*c*) it is not appealed against within the permitted time; or

(*d*) any appeal against it is or is deemed to be withdrawn.

[26/2004]

Variation of licence on application of holder

17. Without affecting any power exercisable by virtue of section 16, the licensing authority 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 licensing authority 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.

Clinical trials and medicinal tests on animals

18. The Minister may by regulations provide for —

(*a*) the conduct of clinical trials, the issue of clinical trial certificates, the exemption of clinical trials from sections 5 and 6, and matters relating to any consent for a subject to participate in a clinical trial, including —

(i) the persons who may so consent;

(ii) the considerations which any such person must take into account before so consenting;

(iii) the circumstances in which the consent of such person may be relied upon; and

(iv) the circumstances in which no consent of any person is required for the subject's participation in the trial,

and whether any matter so prescribed has effect in addition to or despite any other written law or rule of law;

(*b*) the conduct of medicinal tests on animals, the issue of animal test certificates, the exemption of medicinal tests on animals from sections 5 and 6; and

(*c*) the control, housing and other restrictions in the sale, supply, manufacture, import and export of animal feeding stuffs in which medicinal products are incorporated,

and for any matter ancillary or incidental thereto.

[29/2015]

Provision of information to licensing authority

19.—(1) Where an application has been made to the licensing authority for a licence under this Part the licensing authority, before determining the application, may request the applicant to furnish to the licensing authority any information relating to the application that the licensing authority may consider necessary and, where any such request has been made the licensing authority is not required to determine the application until either —

(*a*) the information requested has been furnished to the licensing authority; or

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

(2) The licensing authority may serve on the holder of a licence under this Part, a notice requiring the licence holder, within the time specified in the notice, to furnish to the licensing authority information of any description specified in the notice.

Protection of confidential supporting information about innovative medicinal product

19A.—(1) Where the licensing authority receives, or has received not more than 5 years before 16 April 1998, an innovative medicinal product application and confidential supporting information, the licensing authority, during the protected period in relation to that confidential supporting information —

(*a*) must take reasonable steps to ensure that that confidential supporting information is kept confidential to the licensing authority; and

(*b*) must not use that confidential supporting information for the purposes of determining whether to grant any other application.

[7/98]

(2) In this section and section 19B, unless the context otherwise requires —

"application" means an application for a product licence;

"confidential information" includes —

(*a*) trade secrets; and

(*b*) information that has commercial value that would be, or would be likely to be, diminished by disclosure;

"confidential supporting information" means confidential information given —

(*a*) in, or in relation to, an innovative medicinal product application; and

(*b*) about the medicinal product that is or was (as the case may be) the subject of that application;

"innovative medicinal product application" means —

(*a*) in relation to an application made after 16 April 1998, an application that refers to a substance —

(i) that is an ingredient in the manufacture or preparation of the medicinal product to which the application relates; and

(ii) that has not, before that application is received by the licensing authority, been referred to in any other application as an ingredient in the manufacture or preparation of the medicinal product; and

(*b*) in relation to an application made before 16 April 1998, an application that referred to a substance —

(i) that is or was (as the case may be) an ingredient in the manufacture or preparation of the medicinal product to which the application related; and

(ii) that had not, before that application was received by the licensing authority, been referred to in any other application as an ingredient in the manufacture or preparation of the medicinal product;

"licensing authority" includes any officer designated by the licensing authority under section 4(2) to determine an application for a product licence;

"protected period", in relation to confidential supporting information relating to an innovative medicinal product application received by the licensing authority, means a period of 5 years from the date the innovative medicinal product application is or was (as the case may be) received by the licensing authority.

[7/98]

Circumstances where protection under section 19A does not apply

19B.—(1) Despite section 19A, the licensing authority may, during the protected period in relation to confidential supporting information —

(*a*) disclose that confidential supporting information, or use that confidential supporting information for the purposes of determining whether to grant any application other than

the application to which it relates or related, as the case may be —

(i) with the consent of the applicant who made the application to which the confidential supporting information relates or related; or

(ii) if that disclosure or use is, in the opinion of the licensing authority, necessary to protect the health or safety of members of the public;

(*b*) disclose that confidential supporting information to —

(i) a Government department or statutory body for the purposes of the Government department or statutory body; or

(ii) any adviser engaged by the licensing authority to advise on any aspect of the medicinal product to which the confidential supporting information relates or is related,

if, in the opinion of the licensing authority, the Government department, statutory body or adviser (as the case may be) will take reasonable steps to ensure the confidential supporting information is kept confidential; or

(*c*) disclose that confidential supporting information to any one or more of the following:

(i) the World Health Organisation;

(ii) the Food and Agriculture Organisation;

(iii) any regulatory agency of a WTO Country;

(iv) any advisory committee established under section 73;

(v) any person or organisation, or a person or organisation within a class or classes of persons or organisations, approved by regulations made under this Act, if the disclosure is in accordance with any conditions that may be specified in the regulations.

[7/98]

(2) The power to grant consent under subsection (1)(*a*)(i) may be exercised by a person other than the applicant mentioned in that subsection if —

(*a*) that applicant —

(i) has notified the licensing authority in writing that that other person may grant that consent; and

(ii) has not notified the licensing authority in writing that that person's authority to grant that consent has been withdrawn; or

(*b*) that applicant's rights in respect of the relevant confidential supporting information have been transferred to that person and the applicant or that other person has notified the licensing authority in writing of the transfer.

[7/98]

(3) In this section, "WTO Country" means a country that is a party to the Agreement establishing the World Trade Organisation adopted at Marrakesh on 15 April 1994.

[7/98]

Licensing authority may publish information on applications

19C.—(1) Despite any restriction on the disclosure of information imposed by any written law or rule of law, the licensing authority may from time to time publish, for the information of the public and in the manner determined by it, such particulars of applications for licences which it received as it may determine.

[26/2004]

(2) The particulars mentioned in subsection (1) excludes —

(*a*) any trade secret; and

(*b*) any information that has commercial value that would be, or would be likely to be, diminished by disclosure.

[26/2004]

No product licence to be granted on basis of previous grant

19D.—(1) Where —

(*a*) information has been provided by an applicant for a product licence to the licensing authority relating to the safety or efficacy of a medicinal product in support of such application; and

(*b*) a product licence has been granted in respect of that medicinal product (called in this section the earlier licence),

the licensing authority may not, for a period of 5 years from the date of the grant, grant a product licence to another person in respect of that or a similar medicinal product on the basis of the grant of the earlier licence unless the holder of the earlier licence has given consent to the grant on that basis.

[26/2004]

(2) This section applies where the earlier licence is granted —

(*a*) on or after 1 July 2004; or

(*b*) at any time before 1 July 2004 but no earlier than 5 years before that date.

[26/2004]

Offences under this Part

20.—(1) Subject to section 21, any person who contravenes any of the provisions of sections 5 and 6, or who is in possession of any medicinal product for the purpose of selling, supplying or exporting it in contravention of any of those sections, shall be guilty of an offence.

(2) Where any medicinal product is imported in contravention of section 5, 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 product knowing or having reasonable cause to suspect that it was so imported shall be guilty of an offence.

(3) Any person who, when making an application under section 11 or a declaration under section 12A(2) or giving any information which that person is required to give under section 19, makes a

statement which that person knows or has reason to believe is false in a material particular, shall be guilty of an offence.

[26/2004]

(4) Any person who, when required to furnish to the licensing authority any evidence or document under section 12A(3), furnishes to the licensing authority any thing which that person knows or has reason to believe is forged or altered, shall be guilty of an offence.

[26/2004]

(5) Any person who without reasonable excuse fails to comply with a requirement imposed on that person by a notice under section 19(2) shall be guilty of an offence.

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

[17/2005]

(7) Any person guilty of an offence under subsection (5) shall be liable on conviction to a fine not exceeding $2,000.

Special defences under section 20

21.—(1) Where the holder of a product licence is charged with an offence under section 20 in respect of any medicinal product which has been 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 which are applicable to it, it is a defence for the licence holder to prove —

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

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

(2) Where the holder of a manufacturer's licence is charged with an offence under section 20 in respect of any medicinal products which have been manufactured or assembled by the licence holder, in circumstances where the licence holder is not the holder of a product licence which is applicable to those products, but the products were manufactured or assembled to the order of another person, it is a

defence for the licence holder to prove that the licence holder believed, and had reasonable grounds for believing —

(*a*) that the other person in question was the holder of a product licence applicable to those products; and

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

Certificates for exporters of medicinal products

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

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

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

PART 3

FURTHER PROVISIONS RELATING TO DEALINGS WITH MEDICINAL PRODUCTS

General sale list

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

Sale or supply of medicinal products not on general sale list

24. Subject to any exemption conferred by or under this Part, on and after 3 May 1993, a person must not 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 that person is or acts under the personal supervision of a pharmacist.

[4/2021]

Sale or supply of medicinal products on general sale list

25. This Act does not 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 any conditions that may be prescribed for the purposes of this section.

Prohibition of sale of medicinal products from automatic machines

26. On and after 3 May 1993, a medicinal product must not 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 any conditions that may be prescribed.

Exemptions for doctors, dentists and veterinary surgeons and in respect of herbal remedies

27.—(1) The restrictions imposed by section 24 do not apply to the supply of a medicinal product —

(*a*) by a doctor or dentist to his or her patient; or

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

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

(3) The restrictions imposed by that section do not apply to anything done at 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, and which consists of the 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 diluting with water, but not any other process.

Power to extend or modify exemptions

28.—(1) The Minister may by order provide that section 24 has effect subject to such exemptions (other than those for the time being having effect by virtue of section 27) as may be specified in the order.

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

(3) The Minister may by order provide that section 27 has effect subject to such exceptions or modifications as may be specified in the order.

Medicinal products on prescription only

29.—(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 must state which of the following are to be appropriate practitioners for the purposes of this section:

(*a*) doctors;

(*b*) dentists;

(*c*) veterinary surgeons.

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

(*a*) a person must not sell by retail, or supply in circumstances corresponding to retail sale, a medicinal product of a description, or falling within a class, specified in an order under this section except in accordance with a prescription given by an appropriate practitioner;

(*b*) a person must not administer (otherwise than to himself or herself) any such medicinal product unless the person 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 subsection (2)(*a*) and (*b*), has effect subject to any exemptions that may be specified in the order; or

(*b*) that, for the purpose of subsection (2)(*a*), a medicinal product must not be taken to be supplied in accordance with a prescription given by an appropriate practitioner unless the conditions that are prescribed 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 or limitations as may be specified in the order.

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

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

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

(*b*) prohibit the sale or supply, or the import, 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 order under this section may be a total prohibition or may be imposed subject to any exceptions that may be specified in the order.

Adulteration of medicinal products

31. A person must not —

(*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 is to be sold or supplied in that state; or

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

Protection of purchasers of medicinal products

32.—(1) A person must not, to the prejudice of the purchaser, sell any medicinal product which is not of the nature or quality demanded by the purchaser.

(2) For the purposes of this section the sale of a medicinal product must 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) must not be taken to be contravened by reason only that a medicinal product contains some extraneous matter, if it is proved that the presence of that matter was an inevitable consequence of the process of manufacture of the product.

(4) Subsection (1) must 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 pursuant to a prescription given by a practitioner, subsections (1) to (4) have effect as if —

(*a*) in those provisions any reference to sale included a reference to supply and (except as provided by 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 "demanded by the purchaser", there were substituted the words "specified in the prescription".

Compliance with standards specified in monographs in certain publications

33.—(1) A person must not —

(*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 pursuant to 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) A person must not 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 must 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) In this section "publication" means one of the following, that is to say, the *British Pharmacopoeia*, the *European Pharmacopoeia* or the *United States Pharmacopoeia*, the *British Pharmaceutical Codex* and the *British Veterinary Codex*; and "the 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 that name, there was specified a particular edition of a particular publication, means the monograph 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 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 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 "the 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 *European Pharmacopoeia* or the *United States Pharmacopoeia*; or

(*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*.

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

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

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

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

(7) The Minister may by order amend subsections (4), (5) and (6).

Further powers to regulate dealings with medicinal products

34.—(1) The Minister may by regulations prescribe any requirements that the Minister may consider necessary or expedient with respect to any of the following matters:

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

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

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

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

whom medicinal products are sold or supplied or for whom medicinal products are being prepared or assembled;

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

(*f*) the safekeeping of medicinal products;

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

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

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

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

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

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

(2) Without limiting subsection (1), the regulations 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.

Offences under this Part

35.—(1) Any person who contravenes section 24, 26, 29, 31, 32 or 33 or who contravenes any order made under section 30, shall be guilty of an offence.

(2) Where a medicinal product is sold, supplied or imported in contravention of an order made under section 30, 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, shall be guilty of an offence.

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

(4) Any person who contravenes any conditions prescribed for the purpose of section 25 shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $2,000.

36. to **43.** [*Repealed by Act 4 of 2021*]

PART 4

CONTAINERS, PACKAGES AND IDENTIFICATION OF MEDICINAL PRODUCTS

Labelling and marking of containers and packages

44.—(1) The Minister may by regulations impose any requirements that the Minister considers necessary or expedient with respect to any of the following matters:

(*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) A person must not sell or supply any medicinal product in such circumstances as to contravene any requirements imposed by the regulations mentioned in subsection (1).

(3) Insofar 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 it being enclosed in a container is, except insofar as the

regulations otherwise provide, taken to contravene those requirements as if the person had sold or supplied it in a container not complying with those requirements.

(4) Without affecting subsections (1), (2) and (3), a person must not sell or supply a medicinal product of any description in a container or package which is labelled or marked in such a way that the container or package —

(*a*) falsely describes the product; or

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

Leaflets

45.—(1) The Minister may by regulations impose any requirements that 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) A person must not supply with any medicinal products, or have in the person's possession for the purpose of so supplying, a leaflet which contravenes any requirements imposed by the regulations mentioned in subsection (1).

(3) Without affecting subsections (1) and (2), a person must not supply with a medicinal product of any description, or have in the person's 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.

Requirements as to containers

46.—(1) The Minister may by regulations prohibit the sale or supply of medicinal products otherwise than in containers which comply with any requirements that the Minister considers necessary

or expedient and in particular 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) A person must not sell or supply, or have in the person's possession for the purpose of sale or supply, any medicinal product in such circumstances as to contravene any requirements imposed by the regulations mentioned in subsection (1).

Distinctive colours, shapes and markings of medicinal products

47.—(1) The Minister may by regulations impose any requirements that the Minister considers necessary or expedient with respect to any one or more of the following matters:

(*a*) the colour of medicinal products;

(*b*) the shape of medicinal products;

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

(2) The regulations mentioned in subsection (1) may provide that medicinal products of any such description, or falling within any such class, as may be specified in the regulations must 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) A person must not sell or supply, or have in the person's possession for the purpose of sale or supply, any medicinal product which contravenes any requirements imposed by the regulations mentioned in subsection (1).

Offences under this Part and supplementary provisions

48. Any person who contravenes section 44(2), (3) or (4), 45(2) or (3), 46(2) or 47(3) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $5,000 or to imprisonment for a term not exceeding 2 years or to both.

PART 5

PROMOTION OF SALES OF MEDICINAL PRODUCTS AND MEDICAL ADVERTISEMENTS

Scope of this Part

49.—(1) Subject to the following provisions of this section, in this Part "advertisement" includes every form of advertising, whether in a publication, or by the display of any notice or signboard, 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 a cinematograph film, or by way of sound recording, sound broadcasting or television, or in any other way, and any reference to the issue of an advertisement is to be construed accordingly.

(2) Despite subsection (1), in this Part "advertisement" does not include spoken words except —

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

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

(3) Except as provided by section 52, for the purposes of this Part neither of the following is to 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.

(4) In this Part —

"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 other than words falling within subsection (2)(*a*) or (*b*), and any reference to making a representation is to be construed accordingly.

False or misleading advertisements and representations

50.—(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 shall be guilty of an offence.

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

(3) Subject to the following provisions of this section, any person who makes a false or misleading representation relating to a medicinal product in connection with the sale of that product shall be 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 the practitioner to prescribe or supply medicinal products of that description;

(*b*) to a patient or client of a 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.

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

(*a*) in connection with the 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 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,

that person, subject to the following provisions of this section, shall be guilty of an offence.

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

(*a*) where the offence charged is under subsection (1) or (3), that the person 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 the person 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 it contains an accurate statement of the composition of medicinal products of the description in question or not) is to 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 is to be construed in a corresponding way.

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

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

Prohibition of certain medical advertisements

51.—(1) A person must not 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 First 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*) practitioners;

(*b*) pharmacists;

(*c*) nurses and midwives;

(*d*) persons undergoing training with a view to becoming practitioners, pharmacists or nurses and midwives.

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

(4) The Minister may by order —

(*a*) amend the First Schedule; and

(*b*) exempt any advertisement or class of advertisements from subsection (1).

Powers to regulate advertisements and representations

52.—(1) The Minister may by regulations prohibit any one or more of the following:

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

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

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

(*d*) the issue of advertisements relating to medicinal products and containing a word or phrase specified in the regulations, as being a word or phrase which, in the opinion of the 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) Without affecting subsection (1), the Minister may by regulations impose any requirements that the Minister considers necessary or expedient with respect to any one or more of the following matters:

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

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

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

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

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

Power of licensing authority to require copies of advertisements

53.—(1) The licensing authority may serve on any person a notice requiring that person, within the time specified in the notice, to furnish to the licensing 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 12 months ending with the date of service of the notice.

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

PART 6

MISCELLANEOUS AND SUPPLEMENTARY PROVISIONS

Application of this Act to certain articles and substances

54.—(1) The Minister may by order —

(*a*) 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 or for a cosmetic; and

(*b*) direct that, subject to any exceptions and modifications specified in the order, such provisions of this Act as may be so specified (including provisions so specified which relate to offences or penalties) are to have effect in relation to articles or substances of that description or class as those provisions have effect in relation to medicinal products.

(2) An order under subsection (1) may —

(*a*) apply to any class or description of chewing gum that is intended for use in promoting dental health or oral hygiene; and

(*b*) require the chewing gum to be sold or supplied by prescription or by or under the supervision of a pharmacist.

[26/2004]

(3) In this section, "cosmetic" means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance, and includes a deodorant or any depilatory substance but does not include a soap.

Application of this Act to certain other substances which are not medicinal products

55. 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 Act as may be so specified (including any provisions so specified which relate to offences or penalties) are to have effect in relation to that substance as those provisions have effect in relation to medicinal products.

Rights of entry

56.—(1) Any person duly authorised in writing by the licensing 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 any provisions of this Act or of any regulations or orders made under this Act;

(*b*) enter any premises generally for the purposes of the performance by the authority of the authority's functions under this Act or under any regulations or orders made under this Act; or

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

(2) Without limiting subsection (1), any person duly authorised in writing by the licensing authority may at any reasonable time enter any premises occupied by an applicant for a licence or certificate or for renewal thereof under Part 2 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

57.—(1) For the purpose of ascertaining whether there is or has been a contravention of this Act or any regulations or orders made under this Act, any person duly authorised in writing by the licensing authority (called in this section an authorised person) may inspect —

(*a*) any substance or article appearing to the authorised person to be a medicinal product;

(*b*) any article appearing to the authorised person 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 the authorised person 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 the purpose specified in subsection (1) an authorised person requires a sample of any substance or article appearing to the authorised person 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 authorised person may take a sample of that substance or article.

(3) For the 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 the business which are in that person's possession or under that person's control; and

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

(4) An authorised person may 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 Act 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 Act.

(5) An authorised person may, so far as is reasonably necessary in order to secure that the provisions of this Act and any regulations or orders made under this Act 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 the authorised person to do so.

(6) Where an authorised person seizes any substance or article (including any document) under subsection (4), that authorised person must 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) The Minister may by regulations prescribe the procedure for the sampling of articles and substances seized under this section.

Supplementary provisions as to rights of entry and related rights

58.—(1) Any person entering any property (that is to say, any premises, ship, aircraft, vehicle, stall or place) by virtue of section 56 may take with the person such other persons and such equipment as may appear to the person to be necessary.

(2) Any person who —

(*a*) wilfully obstructs a person acting pursuant to this Act and duly authorised so to act by the licensing authority; or

(*b*) wilfully fails to comply with any requirement properly made to the person by a person so acting under section 57; or

(*c*) without reasonable cause fails to give to a person so acting any other assistance or information which that person may reasonably require of him or her for the purpose of the performance of his or her functions under this Act,

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

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

Seizure or detention of goods subject to prohibition or restriction

59.—(1) Any imported goods are deemed to be imported contrary to a prohibition or restriction for the time being in force 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 purposes of this section; and

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

(2) Any exported goods are deemed to be exported contrary to a prohibition or restriction for the time being in force 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 purposes of this section; and

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

(3) An officer of customs or 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

60.—(1) Whenever any goods are seized under this Act, the seizing officer must forthwith give written notice of the seizure to the owner of the goods, if known, either by delivering the notice to the owner personally or by post at the owner's place of residence if known:

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

(2) An order for the forfeiture of any goods is to be made if it is proved to the satisfaction of a court that an offence under this Act has been committed and that the goods were the subject matter of or was used in the commission of the offence even though 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 are deemed to be forfeited at the expiry of one month from the date of the seizure of the goods unless a claim to the goods has been made before that date in the manner prescribed.

Disposal of goods forfeited

61.—(1) All goods which are forfeited under this Act must be disposed of in the manner that the licensing authority thinks fit.

[4/2001]

(2) The licensing authority 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 under this Act.

[4/2001]

Restrictions on disclosure of information

62.—(1) If any person discloses to any other person —

(*a*) any information with respect to any manufacturing process or trade secret obtained by the firstmentioned person in premises which the firstmentioned person has entered by virtue of section 56; or

(*b*) any information obtained by or furnished to the firstmentioned person pursuant to this Act,

the firstmentioned person shall, unless the disclosure was made in the performance of the firstmentioned person's duty, be guilty of an offence.

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

Protection for officers

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

Contravention due to default of other person

64.—(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 firstmentioned 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 firstmentioned person if the firstmentioned person had been convicted of the offence.

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

(*a*) that the person 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 firstmentioned person must be acquitted of the offence.

(3) This section applies to sections 31 to 33, 44 to 47 and 50 to 52 and the provisions of any regulations made under any of those sections.

Warranty as defence

65.—(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 is a defence for the accused to prove —

(*a*) that the accused purchased the substance or article to which the contravention relates in Singapore 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 the accused sold or supplied and with a written warranty to that effect;

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

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

(2) This section applies to section 31(*b*), sections 32, 33 and 44 to 47 and the provisions of any regulations made under any of those sections.

(3) A warranty is not a defence by virtue of this section unless the accused has, not later than 7 clear days before the date of the hearing, sent to the prosecution a copy of the warranty with a notice stating that the accused intends to rely on it and specifying the name and address of the person from whom the accused received it, and has also 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 or she is entitled to rely on this section in the same way as his or her employer would have been entitled to do if the employer had been charged with the offence.

(5) The person by whom the warranty is alleged to have been given is entitled to appear at the hearing and to give evidence, and the court may, if it thinks fit, adjourn the hearing to enable the person 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

66.—(1) If an accused in any such proceedings as are mentioned in section 65(1) wilfully applies to any substance or article a warranty given in relation to a different substance or article the accused shall be guilty of an offence.

(2) A person who, in respect of any substance or article sold by the person in respect of which a warranty might be pleaded under section 65, gives to the purchaser a false warranty in writing shall be guilty of an offence, unless the person proves that when the person gave the warranty the person had reason to believe that the statement or description contained in it was accurate.

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

Offences by bodies corporate

67. Where an offence under this Act 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.

Certificate of analysis

68. In any proceedings under this Act a certificate of analysis purporting to be signed by an analyst is, on its production by the prosecution without proof of the signature of the analyst, sufficient evidence of the facts stated in the certificate until the contrary is proved.

Presumptions

69.—(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 24 or any conditions prescribed for the purpose of section 25; or

(*b*) offering a medicinal product for sale in contravention of section 31(*b*),

where it is proved that the medicinal product in question was found on a vehicle or stall from which medicinal products are sold, it is presumed, unless the contrary is proved, that the person in charge of the vehicle or stall offered that medicinal product for sale and, in a case falling within paragraph (*a*), that the person 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 the person's 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 that person's control, it is presumed, unless the contrary is proved, that that person had that medicinal product in that person's possession for the purpose of sale or supply.

(3) Subsection (2) applies to sections 31(*b*), 44(2) and (4), 46(2) and 47(3).

(4) For the purposes of any proceedings under this Act for an offence consisting of a contravention of section 45(2) or (3), as relates 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 the person's control, it is presumed, unless the contrary is proved, that the person had the leaflet in the person's possession for the purpose of supplying it with a medicinal product.

Service of documents

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

(*a*) by delivering it to that person;

(*b*) by sending it by post to that person at that person's usual or last known residence or place of business in Singapore; 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 sending it by post to the secretary of that body corporate at the office.

Jurisdiction of District and Magistrate's Courts

71. Despite anything to the contrary contained in the Criminal Procedure Code 2010, a District Court or Magistrate's Court has jurisdiction to try any offence under this Act and to impose the full penalty or punishment in respect of any such offence.

Composition of offences

72. The licensing authority may compound any offence under this Act or any regulations made under this Act by accepting from the person reasonably suspected of having committed the offence a sum not exceeding $2,000.

Fees, charges, etc., collected by licensing authority to be paid to appropriate Authority

72A. All fees, charges and other moneys recovered or collected by the licensing authority under this Act or any regulations made under this Act (including sums collected for the composition of offences under section 72) must be paid —

(*a*) in the case where the licensing authority is the Chief Executive of the Authority, to the Authority; and

(*b*) in the case where the licensing authority is the Director-General, Animal Health and Welfare, to the National Parks Board established by the repealed National Parks Act (Cap. 198A, 1991 Revised Edition) as in force before 1 July 1996 and continued by section 3 of the National Parks Board Act 1996.

[4/2001; 10/2019]

Advisory committees

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

Regulations

74.—(1) The Minister may make regulations for any purpose for which regulations are authorised or required to be made under this Act and generally for carrying out the purposes and provisions of this Act.

(2) Without limiting subsection (1), regulations made under this Act may —

(*a*) prescribe fees for the grant or renewal of licences and certificates;

(*b*) prescribe standard provisions for licences and certificates either in respect of medicinal products generally or any class of medicinal products;

(*c*) provide for the registration of premises, other than pharmacies, used for the purpose of the retail sale, storage or supply of medicinal products; and

(*d*) provide that any person who contravenes the regulations shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $5,000 or to imprisonment for a term not exceeding 2 years or to both.

Application of other written law not affected

75. Except as expressly provided in this Act, this Act does not limit or affect in any way the provisions or operation of any other written law relating to any matter which may be dealt with in this Act.

Repeal and consequential amendments

76.—(1) *The Medicines (Advertisement and Sale) Act 1955 and the Sale of Drugs Act 1914 are repealed and any subsidiary legislation made under those Acts are revoked.*

Second Schedule

(2) *The Poisons Act 1938 is amended in the manner set out in the Second Schedule.*

Act not to apply to products categorised and regulated as health products under Health Products Act 2007

77.—(1) Where any product to which this Act applies has been categorised as a type of health product under the Health Products Act 2007, the Minister may, by order in the *Gazette*, declare that the provisions of this Act cease to apply to that type of product as from the date specified in the order, and the provisions of this Act, as from the date so specified, cease to apply to that type of product.

[15/2007]

(2) The Minister may, in making any order under subsection (1), prescribe such transitional, saving and other consequential provisions as the Minister may consider necessary or expedient.

[15/2007]

FIRST SCHEDULE

Section 51(1)(*a*) and 51(4)(*a*)

DISEASES AND CONDITIONS

1. Blindness
2. Cancer
3. Cataract
4. Drug addiction

FIRST SCHEDULE — *continued*

5. Deafness
6. Diabetes
7. Epilepsy or fits
8. Hypertension
9. Insanity
10. Kidney diseases
11. Leprosy
12. Menstrual disorders
13. Paralysis
14. Tuberculosis
15. Sexual function
16. Infertility
17. Impotency
18. Frigidity
19. Conception and pregnancy

SECOND SCHEDULE

Section 76(2)

AMENDMENTS TO THE POISONS ACT 1938

1. In section 6 —

(*a*) delete the word "and" appearing at the end of subsection (1)(a)(iv);

(*b*) delete subsection (1)(a)(v); and

(*c*) delete the words "or to some pharmacist in the employment of the seller at the premises where the sale is effected," appearing in the second, third and fourth lines of subsection (3)(a).

2. Section 7 is repealed.

3. In section 9(3), delete the words "or for dispensing purposes" appearing in the first and second lines.

4. In section 11(1) —

(*a*) delete the words "; or" appearing at the end of paragraph (c) and substitute therefor a full-stop; and

SECOND SCHEDULE — *continued*

(*b*) delete paragraph (d).

5. In section 17(1), delete the words "sections 7 and" appearing in the fourth line and substitute therefor the word "section".

6. In section 21(1) —

(*a*) delete the words "(c) or (d)" appearing in the third line of sub-paragraph (i) of paragraph (c);

(*b*) delete sub-paragraph (ii) of paragraph (c); and

(*c*) delete paragraphs (g) and (i).

7. After section 21, insert the following:

"**Non-application of this Act to medicinal product or substance**

22. Nothing in this Act shall apply 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 the Medicines Act 1975.".

LEGISLATIVE HISTORY
MEDICINES ACT 1975

This Legislative History is a service provided by the Law Revision Commission on a best-efforts basis. It is not part of the Act.

1. Act 52 of 1975 — Medicines Act, 1975

Bill	:	12/1975
First Reading	:	3 March 1975
Second Reading	:	27 March 1975
Select Committee Report	:	Parl. 8 of 1975
Third Reading	:	20 November 1975
Commencement	:	24 June 1977 (Parts I and II, sections 30, 31, 34, and 35 of Part III, Part V and sections 54 to 75 of Part VII) 15 November 1977 (Part VI) 16 January 1981 (Part IV) 3 May 1993 (Part III except sections 30, 31, 34 and 35)

2. 1985 Revised Edition — Medicines Act (Chapter 176)

Operation	:	30 March 1987

3. Act 7 of 1998 — Medicines (Amendment) Act 1998

Bill	:	5/1998
First Reading	:	14 January 1998
Second and Third Readings	:	19 February 1998
Commencement	:	16 April 1998

4. Act 16 of 2000 — Agri-food and Veterinary Authority Act 2000
(Amendments made by section 47 read with item (6) of the Schedule to the above Act)

Bill	:	11/2000
First Reading	:	21 February 2000
Second and Third Readings	:	17 March 2000
Commencement	:	1 April 2000 (section 47 read with item (6) of the Schedule)

5. Act 46 of 1999 — Nurses and Midwives Act 1999
(Amendments made by section 51 read with item (2) of the Schedule to the above Act)

Bill	:	38/1999
First Reading	:	11 October 1999
Second and Third Readings	:	24 November 1999
Commencement	:	1 May 2000 (section 51 read with item (2) of the Schedule)

6. Act 4 of 2001 — Health Sciences Authority Act 2001
(Amendments made by section 42 read with item (7) of the Second Schedule to the above Act)

Bill	:	3/2001
First Reading	:	12 January 2001
Second and Third Readings	:	22 February 2001
Commencement	:	1 April 2001 (section 42 read with item (7) of the Second Schedule)

7. Act 26 of 2004 — Medicines (Amendment) Act 2004

Bill	:	25/2004
First Reading	:	19 May 2004
Second and Third Readings	:	15 June 2004
Commencement	:	1 July 2004

8. Act 17 of 2005 — Statutes (Miscellaneous Amendments and Repeal) Act 2005
(Amendments made by section 7 of the above Act)

Bill	:	7/2005
First Reading	:	18 April 2005
Second and Third Readings	:	16 May 2005
Commencement	:	15 July 2005 (section 7)

9. Act 15 of 2007 — Health Products Act 2007
(Amendments made by section 76 of the above Act)

Bill	:	3/2007
First Reading	:	22 January 2007
Second and Third Readings	:	12 February 2007

Commencement	:	1 November 2007 (section 76)

10. Act 22 of 2007 — Dentists (Amendment) Act 2007
(Amendments made by section 39 read with item (6) of the Schedule to the above Act)

Bill	:	9/2007
First Reading	:	27 February 2007
Second and Third Readings	:	12 April 2007
Commencement	:	1 January 2008 (section 39 read with item (6) of the Schedule)

11. Act 48 of 2007 — Pharmacists Registration Act 2007
(Amendments made by section 76 read with item (2) of the Second Schedule to the above Act)

Bill	:	36/2007
First Reading	:	27 August 2007
Second and Third Readings	:	20 September 2007
Commencement	:	1 September 2008 (section 76 read with item (2) of the Second Schedule)

12. Act 29 of 2015 — Human Biomedical Research Act 2015
(Amendments made by section 67 of the above Act)

Bill	:	25/2015
First Reading	:	13 July 2015
Second Reading	:	17 August 2015
Third Reading	:	18 August 2015
Commencement	:	1 July 2016 (section 67)

13. Act 10 of 2019 — National Parks Board (Amendment) Act 2019
(Amendments made by section 13 of the above Act)

Bill	:	4/2019
First Reading	:	15 January 2019
Second and Third Readings	:	12 February 2019
Commencement	:	1 April 2019 (section 13)

14. Act 4 of 2021 — Statute Law Reform Act 2021
(Amendments made by section 25 of the above Act)

Bill	:	45/2020

First Reading	:	3 November 2020
Second and Third Readings	:	5 January 2021
Commencement	:	1 March 2021 (section 25)

15. 2020 Revised Edition — Medicines Act 1975

Operation	:	31 December 2021

16. G.N. No. S 759/2022 — Revised Edition of the Laws (Rectification of Acts) (No. 2) Order 2022

Operation	:	31 December 2021
Publication	:	26 September 2022

Abbreviations

(updated on 29 August 2022)

G.N.	Gazette Notification
G.N. Sp.	Gazette Notification (Special Supplement)
L.A.	Legislative Assembly
L.N.	Legal Notification (Federal/Malaysian)
M.	Malaya/Malaysia (including Federated Malay States, Malayan Union, Federation of Malaya and Federation of Malaysia)
Parl.	Parliament
S	Subsidiary Legislation
S.I.	Statutory Instrument (United Kingdom)
S (N.S.)	Subsidiary Legislation (New Series)
S.S.G.G.	Straits Settlements Government Gazette
S.S.G.G. (E)	Straits Settlements Government Gazette (Extraordinary)

COMPARATIVE TABLE

MEDICINES ACT 1975

This Act has undergone renumbering in the 2020 Revised Edition. This Comparative Table is provided to help readers locate the corresponding provisions in the last Revised Edition.

2020 Ed.	1985 Ed.
—	**7**—(2) [*Deleted by Act 4 of 2021*]
7—(2)	(3)
(3)	(4)
(4)	(5)
(5)	(6)
16—(2)	**16**—(1A)
(3)	(1B)
(4)	(2)
(5)	(3)
(6)	(4)
20—(4)	**20**—(3A)
(5)	(4)
(6)	(5)
(7)	(6)
—	**PART 4**
PART 4	**PART 5**
PART 5	**PART 6**
PART 6	**PART 7**
54—(2)	**54**—(1A)
(3)	(2)
67	**67**—(1)
—	(2) [*Deleted by Act 4 of 2021*]