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HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS (THERAPEUTIC PRODUCTS) REGULATIONS 2016

ARRANGEMENT OF REGULATIONS

In exercise of the powers conferred by sections 71 and 72 of the Health Products Act, the Health Sciences Authority, with the approval of the Minister for Health, makes the following Regulations:

PART 1

PRELIMINARY

Citation and commencement

1. These Regulations are the Health Products (Therapeutic Products) Regulations 2016 and come into operation on 1 November 2016.

Definitions

2.—(1) In these Regulations, unless the context otherwise requires —

"administer", in relation to a substance or article, means to give or apply it to a human being, whether —

(*a*) orally;

(*b*) by injection or by introduction into the body in any other way; or

(*c*) by external application, whether by direct contact with the body or not;

"appropriate non-proprietary name", in relation to an active ingredient of a therapeutic product, means —

(*a*) the name or synonym of the active ingredient described in the relevant monograph appearing in the latest edition of any specified publication;

(*b*) where the active ingredient is not described in a monograph in any specified publication, its international non-proprietary name; or

(*c*) where paragraph (*a*) or (*b*) is not applicable, the accepted scientific name or other name descriptive of the true nature of the active ingredient;

"appropriate quantitative particulars", in relation to a therapeutic product, means —

(*a*) the quantity of each active ingredient, identified by its appropriate non-proprietary name, in each dosage unit of the therapeutic product and expressed in terms of weight, volume, capacity or units of activity; or

(*b*) where there is no dosage unit of the therapeutic product, the quantity of each active ingredient, identified by its appropriate non-proprietary name, in the container of the therapeutic product and expressed in terms of weight, volume, capacity or units of activity or percentage by weight or volume of the total quantity;

"Authority's website" means the Authority's Internet website at http://www.hsa.gov.sg;

"compound", in relation to a therapeutic product, means to formulate, mix, assemble, package or label the therapeutic product, with the intention of dispensing or administering the therapeutic product to a patient in accordance with the written instructions of a qualified practitioner;

"container", in relation to a therapeutic product, means an article or packaging immediately covering the therapeutic product, including any bottle, ampoule, blister pack, sachet, dial dispenser pack, strip pack, syringe, tube, vessel, vial, wrapper or other similar article, but does not include —

(*a*) an article for ingestion; or

(*b*) an outer package or other packaging in which the container is further enclosed;

"dispense", in relation to a therapeutic product, means to prepare and supply the therapeutic product to a patient, where the preparation and supply is made by —

(*a*) a qualified practitioner or a person acting under the supervision of a qualified practitioner; or

(*b*) a qualified pharmacist or a person acting under the supervision of a qualified pharmacist;

"expiry date", for a therapeutic product, means the date after which, or the month and year after the end of which, the therapeutic product should not be used;

"general sale list medicine" means a therapeutic product registered under the classification of "general sale list medicine" in the Register of Health Products;

"healthcare institution licence" means a licence issued under section 5(1) of the Private Hospitals and Medical Clinics Act (Cap. 248);

"healthcare institution licensee" means the holder of a healthcare institution licence for a private hospital or medical clinic;

"importer's licence" means an importer's licence authorising the holder of the licence to import a therapeutic product under section 13 of the Act;

"international non-proprietary name", for an active ingredient, means a name which has been selected by the World Health Organization as a recommended international non-proprietary name for the active ingredient;

"licensed healthcare institution" means a healthcare institution that is licensed under the Private Hospitals and Medical Clinics Act;

"licensed importer" means the holder of an importer's licence;

"licensed manufacturer" means the holder of a manufacturer's licence;

"licensed retail pharmacy" means premises specified in a pharmacy licence;

"licensed wholesaler" means the holder of a wholesaler's licence;

"licensee", in relation to a therapeutic product, means a licensed manufacturer, licensed importer or licensed wholesaler;

"manufacturer's licence" means a manufacturer's licence authorising the holder of the licence to manufacture a therapeutic product under section 12 of the Act;

"medical clinic" means a medical clinic that is licensed under the Private Hospitals and Medical Clinics Act;

"non-clinical purpose" means any purpose not involving any application of a therapeutic product on, or use of a therapeutic product by, humans;

"Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme Guide to Good Manufacturing Practice for Medicinal Products" means the text of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme Guide to Good Manufacturing Practice for Medicinal Products as set out on the Authority's website from time to time;

"pharmacy licence" means a licence issued under the Health Products (Licensing of Retail Pharmacies) Regulations 2016 (G.N. No. S 330/2016);

"pharmacy-only medicine" means a therapeutic product registered under the classification of "pharmacy-only medicine" in the Register of Health Products;

"prescription-only medicine" means a therapeutic product registered under the classification of "prescription-only medicine" in the Register of Health Products;

"private hospital" means a private hospital that is licensed under the Private Hospitals and Medical Clinics Act;

"proprietary name" means a word or words used in connection with the sale or supply of a therapeutic product for the purpose of indicating that it is the product of a particular person who manufactures, selects the name of, certifies or deals with the therapeutic product, or offers it for sale or supply;

"psychotropic substance" means a substance specified in the First Schedule;

"qualified pharmacist" means a person who —

(*a*) is registered as a pharmacist under the Pharmacists Registration Act (Cap. 230);

(*b*) holds a valid practising certificate granted under section 23 of that Act; and

(*c*) is in active practice as defined in regulation 2 of the Pharmacists Registration (Practising Certificates) Regulations 2008 (G.N. No. S 438/2008);

"qualified practitioner" means —

(*a*) a registered medical practitioner under the Medical Registration Act (Cap. 174); or

(*b*) a registered dentist under the Dental Registration Act (Cap. 76) whose name appears in the first division of the Register of Dentists maintained and kept under section 13(1)(*a*) of that Act;

"repacking", in relation to the compounding of a therapeutic product, means removing the therapeutic product from the container in which it is originally supplied by its manufacturer and —

(*a*) placing it in a different container; or

(*b*) changing the outer packaging or other packaging in which the container is further enclosed;

"specified publication" means any of the following:

(*a*) the British Pharmacopoeia;

(*b*) the European Pharmacopoeia;

(*c*) the United States Pharmacopoeia and the National Formulary;

"supply by retail sale" means sale by retail and includes exposure or display as an invitation to treat;

"therapeutic product" means a health product categorised as a therapeutic product in the First Schedule to the Act;

"trade description" means any description, statement or indication which, directly or indirectly and by any means given, relates to any of the following matters in respect of a therapeutic product:

(*a*) the quantity, liquid volume or weight of the therapeutic product;

(*b*) the method of manufacture, production, or processing, of the therapeutic product;

(*c*) the characteristics or composition of the therapeutic product;

(*d*) the fitness for purpose (including expiry date), dosage strength, or intended purpose, of the therapeutic product;

(*e*) any physical characteristics or presentation of the therapeutic product not referred to in paragraphs (*a*) to (*d*);

(*f*) the testing of the therapeutic product by any person and the results of the test;

(*g*) the approval of the therapeutic product by any person or its conformity with a product description approved by any person;

(*h*) the place or date of manufacture, production, or processing, of the therapeutic product;

(*i*) the name of the person who manufactured, produced or processed the therapeutic product;

"wholesaler's licence" means a wholesaler's licence authorising the holder of the licence to supply a therapeutic product by wholesale under section 14 of the Act.

(2) For the purposes of these Regulations, a prescription is valid only if the prescription —

(*a*) is written and signed by a qualified practitioner; and

(*b*) contains all of the following particulars:

(i) the date of the prescription;

(ii) the name and address of the qualified practitioner giving the prescription;

(iii) the name, identity card or other identification document number, and contact details, of the patient to whom the prescription relates;

(iv) the name and total amount of the prescribed therapeutic product to be supplied to, and the dose to be taken by, the patient;

(v) where the qualified practitioner giving the prescription intends for the prescription to be repeated, an indication of the number of times, and the time period between which, the prescribed therapeutic product may be supplied;

(vi) where the prescription is given by a dentist, a declaration by the dentist that the prescription is "for dental treatment only".

Scope of Regulations

3. These Regulations do not apply to any therapeutic product that is clinical research material as defined in regulation 2(1) of the Health

Products (Therapeutic Products as Clinical Research Materials) Regulations 2016 (G.N. No. S 332/2016).

PART 2

MANUFACTURE AND IMPORT OF THERAPEUTIC PRODUCTS

Division 1 — Manufacture

Requirements for issue of manufacturer's licence

4. For the purposes of section 24(2)(*a*)(i) of the Act, the requirements that must be satisfied for the issue, to an applicant, of a manufacturer's licence for a therapeutic product are that —

(*a*) the applicant is able to provide and maintain, or ensure the provision and maintenance of, such staff, premises, equipment and facilities as are necessary for carrying out the stages of the manufacture of the therapeutic product to be authorised by the licence;

(*b*) the applicant is able to provide and maintain, or ensure the provision and maintenance of, such staff, premises, equipment and facilities for the handling and storage of the therapeutic product as are necessary to prevent the deterioration of the therapeutic product while it is in the applicant's ownership, possession or control;

(*c*) the applicant is able to conduct all manufacturing operations in such a way as to ensure that the therapeutic product is of the correct identity and conforms with the applicable standards of strength, quality and purity for that therapeutic product; and

(*d*) the applicant is able to comply with the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme Guide to Good Manufacturing Practice for Medicinal Products in relation to the manufacture of the therapeutic product.

Division 2 — Import

Requirements for issue of importer's licence

5.—(1) For the purposes of section 24(2)(*a*)(i) of the Act, the requirements that must be satisfied for the issue, to an applicant, of an importer's licence for a therapeutic product are that —

(*a*) the applicant is able to provide and maintain, or ensure the provision and maintenance of, such staff, premises, equipment and facilities for the handling and storage of the therapeutic product as are necessary to prevent the deterioration of the therapeutic product while it is in the applicant's ownership, possession or control;

(*b*) the therapeutic product —

(i) is imported on behalf of a healthcare institution licensee for a private hospital or medical clinic pursuant to a valid prescription given by a qualified practitioner practising at the private hospital or medical clinic for the use of the qualified practitioner's patient;

(ii) is intended to be supplied solely for the purpose of scientific education or research and development, or for a non-clinical purpose;

(iii) is imported solely for the purpose of export;

(iv) is intended to be supplied for use on a ship, and the therapeutic product is one that is required to be carried on board the ship under the Merchant Shipping (Medical Stores) Regulations (Cap. 179, Rg 3), the Merchant Shipping (Maritime Labour Convention) (Medicines and Medical Equipment) Regulations 2014 (G.N. No. S 181/2014) or any other written law, for the treatment of persons on board that ship;

(v) is intended to be supplied for use on an aircraft, and the therapeutic product forms part of the medical supplies required under the Air Navigation Order

(Cap. 6, O 2) or any other written law, for the treatment of persons on board the aircraft;

(vi) is authorised for import by the registrant of the therapeutic product; or

(vii) is in all respects the same as a registered therapeutic product, the registrant of which has not authorised the applicant to import that registered therapeutic product; and

(*c*) the applicant is able to comply with the requirements in the Authority's Guidance Notes on Good Distribution Practice for importers set out on the Authority's website if the therapeutic product is imported in accordance with sub-paragraph (*b*)(i), (vi) and (vii).

(2) In addition to the requirements in paragraph (1), an applicant who intends to import a therapeutic product under paragraph (1)(*b*)(vii) must obtain the Authority's prior approval for each consignment of such therapeutic product to be imported.

(3) An application for the Authority's approval under paragraph (1) must be made in the form and manner specified on the Authority's website.

Import of therapeutic products containing psychotropic substances

6.—(1) Any person who intends to import a therapeutic product that contains a psychotropic substance must obtain the Authority's prior approval for each consignment of such therapeutic product to be imported.

(2) The amount of each consignment of a therapeutic product to be imported under paragraph (1) must not exceed the quantity approved by the Authority.

(3) An application for the Authority's approval under paragraph (1) must be made in the form and manner specified on the Authority's website.

(4) This regulation applies in addition to the requirements in section 13 of the Act.

PART 3

SUPPLY OF THERAPEUTIC PRODUCTS

Requirements for purposes of section 17

7. Divisions 1 to 3 of this Part prescribe the requirements for the supply of therapeutic products, whether registered or not, to give effect to section 17(1) of the Act.

Division 1 — Requirements for wholesale supply of therapeutic products

Export of therapeutic products containing psychotropic substances

8.—(1) Any person who intends to export a therapeutic product that contains a psychotropic substance must obtain the Authority's prior approval for each consignment of such therapeutic product to be exported.

(2) An application for the Authority's approval under paragraph (1) must be made in the form and manner specified on the Authority's website.

(3) This regulation applies in addition to the requirements in section 14 of the Act.

Export of codeine cough preparations

9.—(1) Any person who intends to export a therapeutic product that is a codeine cough preparation must obtain the Authority's prior approval for each consignment of such therapeutic product to be exported.

(2) An application for the Authority's approval under paragraph (1) must be made in the form and manner specified on the Authority's website.

(3) This regulation applies in addition to the requirements in section 14 of the Act.

Wholesale of therapeutic products containing Second Schedule ingredients

10.—(1) This regulation applies to a therapeutic product that —

(*a*) is a preparation containing an active ingredient specified in Part 1 of the Second Schedule;

(*b*) is within any class of therapeutic products specified in Part 2 of that Schedule; or

(*c*) is a preparation containing an active ingredient specified in Part 3 of that Schedule.

(2) A person who supplies by wholesale to another (called the recipient) any therapeutic product in paragraph (1) must —

(*a*) before the supply, be satisfied that the recipient carries on the trade, business or profession stated in the order and that such trade, business or profession is one in which the therapeutic product is used;

(*b*) at the time of the supply, ensure that there is an order in writing, signed by the recipient, stating the recipient's name and address, trade, business or profession, and the name and total quantity of the therapeutic product supplied; and

(*c*) after the supply, insert in the appropriate entry in the record of supply prescribed by regulation 32(2)(*b*) a reference number by which the order can be identified.

(3) Paragraph (2) does not apply to the supply by wholesale of a therapeutic product under regulation 47 or 59.

Division 2 — Requirements for retail supply of registered therapeutic products

Supply by retail sale of prescription-only medicine

11. A person must not supply by retail sale any prescription-only medicine unless —

(*a*) the supply is made at or from a licensed retail pharmacy in accordance with regulation 3(1) and (2) of the Health

Products (Licensing of Retail Pharmacies) Regulations 2016 (G.N. No. S 330/2016);

(*b*) the supply is made at or from a licensed healthcare institution supplying the prescription-only medicine to a patient of that healthcare institution, and in accordance with the written instructions of a qualified practitioner practising in that healthcare institution;

(*c*) the person is a qualified practitioner or a person acting in accordance with the oral or written instructions of a qualified practitioner, and the supply is made to a patient under the care of the qualified practitioner; or

(*d*) the person is specified in the first column of the Third Schedule, the prescription-only medicine is of the type specified in the corresponding paragraph in the second column of that Schedule, and the supply is in accordance with the conditions specified in the corresponding paragraph in the third column of that Schedule.

Supply by administration of prescription-only medicine

12. A person must not administer a prescription-only medicine unless —

(*a*) the person is a qualified practitioner or a person acting in accordance with the oral or written instructions of a qualified practitioner; or

(*b*) the person is specified in the first column of the Third Schedule, the prescription-only medicine is specified in the corresponding paragraph in the second column of that Schedule, and the administration of the prescription-only medicine is in accordance with the conditions specified in the third column of that Schedule.

Supply by retail sale of pharmacy-only medicine

13.—(1) A person must not supply by retail sale any pharmacy-only medicine unless —

(*a*) the supply is made at or from a licensed retail pharmacy in accordance with regulation 3(1) of the Health Products (Licensing of Retail Pharmacies) Regulations 2016 (G.N. No. S 330/2016);

(*b*) the supply is made, at or from a licensed healthcare institution supplying the pharmacy-only medicine to a patient of that healthcare institution, and in accordance with the written instructions of a qualified practitioner practising in that healthcare institution; or

(*c*) the person is a qualified practitioner, or a person acting in accordance with the oral or written instructions of a qualified practitioner, and the supply is made to a patient under the care of the qualified practitioner.

(2) A person who supplies by retail sale any pharmacy-only medicine must keep, at the premises where or from which the medicine is supplied, a record of every such supply, and the record must contain all of the following particulars in relation to each supply:

(*a*) the date of the supply;

(*b*) the name, identity card or other identification document number, and contact details, of the person to whom the pharmacy-only medicine is supplied;

(*c*) the name, strength and total amount of pharmacy-only medicine to be supplied;

(*d*) the dosage, and the frequency and purpose of the treatment for which the supply is made.

(3) The record required under paragraph (2) must be made on the day on which the pharmacy-only medicine is supplied or, if that is not reasonably practicable, within 24 hours after that day, and must be kept for a period of at least 2 years after the date of the supply.

(4) A supplier of a pharmacy-only medicine by retail sale must make available for inspection by the Authority at all reasonable times any record made under paragraph (2).

(5) This regulation does not apply to the supply of any pharmacy-only medicine by administration to, or application in, any person in the course of any diagnosis, treatment or test.

Restrictions on supply by retail sale of codeine cough preparations

14.—(1) A qualified practitioner or qualified pharmacist who supplies by retail sale any codeine cough preparation —

(*a*) must not supply more than a total of 240 ml of any one or more codeine cough preparations to any one individual on any one occasion;

(*b*) must not supply any codeine cough preparation to the same individual more than once within a period of 4 days (including Sundays and public holidays); and

(*c*) must, on each occasion of the supply of the codeine cough preparation by the qualified pharmacist to an individual, provide professional counselling on the use of the codeine cough preparation.

(2) In this regulation, "codeine cough preparation" means any medicine in liquid form that contains codeine and is intended by the manufacturer for the treatment of coughs.

Supply of general sale list medicine by retail sale vending machine

15. A person may supply by retail sale any general sale list medicine by means of an automatic vending machine, if all of the following requirements are satisfied:

(*a*) the person's name and contact information is prominently displayed on the automatic vending machine;

(*b*) the automatic vending machine is sufficiently equipped and secure to ensure appropriate storage conditions for the medicine;

(*c*) the medicine is labelled and packaged in accordance with the conditions attached by the Authority to the registration of the medicine under the Act;

(*d*) the package size of the medicine is the same as the package size specified for the registration of the medicine, and the total amount of the medicine in each package does not exceed a total dosage of 3 months per individual.

Division 3 — Other requirements for supply of therapeutic products

Records of supply of prescribed therapeutic products

16.—(1) A supplier must, in respect of the supply by retail sale of any therapeutic product prescribed by a qualified practitioner, keep at the premises where or from which the therapeutic product is supplied a record, complying with paragraphs (2) and (3), of every such supply.

(2) The record required under paragraph (1) must contain all of the following particulars:

(*a*) the date of supply;

(*b*) the name, identity card or other identification document number, and contact details, of the person to whom the therapeutic product is supplied;

(*c*) the name of the therapeutic product, being either the proprietary name or the appropriate non-proprietary name, and the total amount supplied;

(*d*) if the therapeutic product is supplied by a qualified pharmacist or a person acting under the supervision of a qualified pharmacist, or at or from a licensed retail pharmacy, the name and address of the qualified practitioner who signed the prescription.

(3) The record in paragraph (1) must be made on the day on which the therapeutic product is supplied or, if that is not reasonably practicable, within 24 hours after that day, and must be kept for a period of at least 2 years after the date of the supply.

(4) A supplier must make available for inspection by the Authority at all reasonable times any record made under paragraph (1).

(5) This regulation does not apply to the supply of any therapeutic product by wholesale.

Supply by dispensing therapeutic products

17.—(1) A relevant person may dispense a therapeutic product only if the package or container of the therapeutic product is labelled with all of the following information in English:

(*a*) the name of the person to whom the therapeutic product is to be administered;

(*b*) the name, address and any identification number or logo of the licensed healthcare institution or licensed retail pharmacy where the therapeutic product is supplied or dispensed;

(*c*) the date that the therapeutic product is dispensed;

(*d*) the directions for use of the therapeutic product;

(*e*) the name of the therapeutic product, being either the proprietary name or the appropriate non-proprietary name;

(*f*) where the appropriate non-proprietary name is included on the label, the appropriate quantitative particulars of any active ingredient of the therapeutic product.

(2) A prescription-only medicine may be dispensed only in accordance with the following requirements:

(*a*) where the qualified practitioner giving the prescription does not specify that the prescription is to be repeated, the relevant person dispensing the prescription-only medicine must —

(i) when dispensing, mark the prescription in a manner so as to permanently attach the person's name and address and the dispensing date to the prescription; and

(ii) retain the prescription for a period of at least 2 years after dispensing; or

(*b*) where the qualified practitioner giving the prescription specifies that the prescription is to be repeated, the relevant person dispensing the prescription-only medicine —

(i) must not dispense more than the total number of times specified on the prescription;

(ii) when dispensing, must mark the prescription in such a manner as to permanently attach the person's name and address and the dispensing date to the prescription; and

(iii) must retain the prescription for a period of at least 2 years after dispensing for the last time.

(3) In this regulation, "relevant person" means —

(*a*) a qualified practitioner or a person acting under the supervision of a qualified practitioner; or

(*b*) a qualified pharmacist or a person acting under the supervision of a qualified pharmacist.

Division 4 — Requirements for wholesaler's licence

Requirements for issue of wholesaler's licence

18. For the purposes of section 24(2)(*a*)(i) of the Act, the requirements that must be satisfied for the issue, to an applicant, of a wholesaler's licence for a therapeutic product are that —

(*a*) the applicant is able to provide and maintain, or ensure the provision and maintenance of, such staff, premises, equipment and facilities for the handling, storage and distribution of the therapeutic product as are necessary to prevent the deterioration of the therapeutic product while it is in the applicant's ownership, possession or control; and

(*b*) the applicant is able to comply with the Authority's Guidance Notes on Good Distribution Practice for wholesalers set out on the Authority's website.

PART 4

PRESENTATION OF THERAPEUTIC PRODUCTS

Trade descriptions

19.—(1) For the purposes of section 18(1) of the Act, the presentation of a therapeutic product must comply with all of the following requirements:

(*a*) a trade description which is false or misleading must not be applied to the therapeutic product;

(*b*) a trade description which explicitly or implicitly suggests that the supply or use of the therapeutic product is promoted or endorsed by the Authority, the Ministry of Health or the Health Promotion Board must not be applied to the therapeutic product.

(2) For the purposes of paragraph (1)(*a*), a trade description is false or misleading if —

(*a*) it contains any false statement or information concerning the therapeutic product; or

(*b*) it is likely to create an erroneous impression regarding the formulation, composition, quality, safety, efficacy or uses of the therapeutic product.

(3) For the purposes of paragraph (1), a person applies a trade description to a therapeutic product if the person —

(*a*) affixes or annexes the trade description to, or in any manner marks it on or incorporates it in —

(i) the therapeutic product; or

(ii) any thing in or on the therapeutic product or with which the therapeutic product is supplied;

(*b*) places the therapeutic product in, on or with any thing which the trade description has been affixed or annexed to, marked on or incorporated in; or

(*c*) makes any oral or written statement of the trade description, or uses the trade description in any other manner, which is

likely to be understood as referring to the therapeutic product.

(4) A person supplying a therapeutic product is taken to have applied a trade description to the therapeutic product if —

(*a*) the therapeutic product is supplied pursuant to a request in which the trade description is used; and

(*b*) it is reasonable in the circumstances to infer that any therapeutic product so supplied will correspond to that trade description.

Information to be provided with therapeutic products

20.—(1) In addition to regulation 19, a therapeutic product must, for the purposes of section 18(1) of the Act, be accompanied by all of the following information, where applicable, when it is supplied:

(*a*) the name of the therapeutic product, being the proprietary name and the appropriate non-proprietary name;

(*b*) the appropriate quantitative particulars of any active ingredient of the therapeutic product;

(*c*) an appropriate control number, such as a serial number, batch number or lot number;

(*d*) the expiry date of the therapeutic product;

(*e*) where the therapeutic product is registered, the registration number assigned to the registered therapeutic product by the Authority.

(2) Where a therapeutic product contains any substance specified in the first column of the Fourth Schedule, the therapeutic product must be labelled with a statement declaring the presence of that substance, and that substance may be described by a corresponding term specified in the second column of that Schedule.

(3) Where a therapeutic product contains any substance specified in the first column of the Fifth Schedule, the therapeutic product must be labelled with the caution set out in the second column of that Schedule.

(4) Where a therapeutic product is contained in a container, which is in the form of a bubble, blister or other sealed unit and is part of a continuous series comprising a sheet or strip of like containers, paragraph (2) or (3), as the case may be, is taken to have been complied with if the statement mentioned in paragraph (2) or the caution mentioned in paragraph (3) is printed or displayed or otherwise marked in a prominent position at frequent intervals on the sheet or strip of the container.

(5) All information accompanying the therapeutic product mentioned in paragraph (1), including the statement mentioned in paragraph (2) and the caution mentioned in paragraph (3) —

(*a*) must be provided in English; and

(*b*) must be legible and indelible.

Corrective measures in relation to contravening trade descriptions or failure to provide prescribed information

21.—(1) Where any manufacturer, importer, supplier or registrant of a therapeutic product has applied a trade description in contravention of regulation 19, the Authority may order that manufacturer, importer, supplier or registrant, as the case may be, to do all or any of the following:

(*a*) to stop disseminating, publishing or using the trade description with immediate effect;

(*b*) to stop applying the trade description to the therapeutic product, or to stop supplying the therapeutic product applied with the trade description, with immediate effect;

(*c*) to take such measures as may be reasonable and necessary in the circumstances to discontinue or remove any trade description that may already have been applied, disseminated, published or used;

(*d*) to apply, disseminate or publish a corrective trade description in such manner and containing such information as the Authority may require.

(2) Where any manufacturer, importer, supplier or registrant of a therapeutic product fails to provide any information required by

regulation 20 to accompany the supply of the therapeutic product, the Authority may order that manufacturer, importer, supplier or registrant, as the case may be, to take such corrective measures as the Authority may require, including —

(*a*) to stop supplying the therapeutic product with immediate effect; or

(*b*) to take such measures as may be reasonable and necessary in the circumstances to ensure that the therapeutic product is only supplied with the required information.

(3) A person to whom an order under paragraph (1) or (2) is directed must comply with the order at the person's own cost and within the time specified in the order or, if no time is specified in the order, within a reasonable time after the date of the order.

(4) A person who fails to comply with paragraph (3) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

(5) Without prejudice to paragraph (4), the Authority may take such steps as the Authority thinks reasonable and necessary to implement the requirements of an order directed to any person under paragraph (1) or (2), and recover any costs and expenses reasonably incurred by the Authority in so doing from the person.

PART 5

REGISTRATION OF THERAPEUTIC PRODUCTS

Requirements for registration

22. For the purposes of section 30(2)(*a*)(iii) of the Act, the Authority may, after carrying out an evaluation under section 33 of the Act, register a therapeutic product, if the Authority is satisfied —

(*a*) that the overall intended benefits to a user of the therapeutic product outweigh the overall risks associated with the use of the therapeutic product; and

(*b*) based on the formulation, manufacturing process controls, specifications and shelf life of the therapeutic product, and the stability of the therapeutic product under the recommended storage conditions, that the therapeutic product is suitable for its intended purpose and that any risk associated with its use is minimised.

Whether therapeutic product subject to patent

23.—(1) In dealing with an application for the registration of a therapeutic product, the Authority must consider whether a patent under the Patents Act (Cap. 221) is in force in respect of the therapeutic product and, if so —

(*a*) whether the applicant for the registration of the therapeutic product is the proprietor of the patent; or

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

(i) the proprietor has consented to or has acquiesced in the grant of the registration of the therapeutic product to the applicant; or

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

(2) Unless the Authority otherwise determines, the applicant must, at the time of the application and at such other time before the determination of the application as the Authority may require, make and furnish to the Authority a declaration in the form specified on the Authority's website, stating —

(*a*) whether a patent under the Patents Act is in force in respect of the therapeutic product; and

(*b*) whether the applicant is the proprietor of the patent.

(3) If the applicant is not the proprietor of the patent in respect of the therapeutic product and there is such a patent in force, the applicant must further state in the declaration mentioned in paragraph (2) —

(*a*) the name and address of the proprietor of the patent;

(*b*) whether —

(i) the proprietor has consented to or has acquiesced in the grant of the registration of the therapeutic product by the applicant; or

(ii) in the opinion of the applicant 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 registration of the therapeutic product is sought; and

(*c*) such other information as the Authority may require in any particular case.

(4) For the purposes of paragraph (1), the Authority may rely upon, and need not be concerned to inquire into the truth of, any statement made in the declaration furnished under paragraph (2).

(5) Where the applicant is not the proprietor of a patent under the Patents Act that is in force in respect of the therapeutic product, the Authority may require the applicant to serve, in accordance with section 67 of the Act, on the proprietor of the patent, a notice in the form specified on the Authority's website, and within such time as the Authority may determine, if —

(*a*) 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 registration is sought; or

(*b*) the Authority considers it appropriate in any particular case for the applicant to do so.

(6) The applicant must furnish to the Authority such evidence of the service of the notice mentioned in paragraph (5) as the Authority may require.

(7) The Authority need not determine the application until the applicant has complied with paragraph (2) and, where applicable, paragraphs (5) and (6), to the reasonable satisfaction of the Authority.

(8) If the Authority is satisfied that the notice mentioned in paragraph (5) has been served on the proprietor of the patent, the Authority may register the therapeutic product if the proprietor does

not, before the 45th day after the date that notice is served on the proprietor —

(*a*) apply to —

(i) a court for an order restraining the act for which the registration of the therapeutic product is sought; or

(ii) a court or the Registrar of Patents or a Deputy Registrar of Patents holding office under the Patents Act, for a declaration that the patent is valid or will be infringed by the doing of the act for which the registration of the therapeutic product is sought; and

(*b*) give written notice to the Authority stating that such application in sub-paragraph (*a*) has been made, accompanied by evidence of the application.

(9) The Authority may register the therapeutic product without further notice to the proprietor of the patent, if no order or declaration mentioned in paragraph (8)(*a*) has been made at the end of 30 months after the date of the application for the order or declaration.

(10) If, before the end of the period mentioned in paragraph (9), the proprietor of the patent submits to the Authority a copy of the order or declaration mentioned in paragraph (8)(*a*), the Authority may refuse to register the therapeutic product.

Cancellation of registration of therapeutic product subject to patent dispute

24.—(1) Without prejudice to the generality of section 37(1) of the Act, the Authority may, upon an application by any interested person, cancel the registration of a therapeutic product, if the Authority is satisfied —

(*a*) that —

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

(ii) a court has determined that the declaration made under regulation 23(2) contains a statement that is false or misleading in a material particular or omits to disclose any matter that is material to the application; and

(*b*) that the determination mentioned in sub-paragraph (*a*)(i) or (ii) is final.

(2) For the purposes of paragraph (1)(*b*), a determination is final if it is not subject to further appeal.

Offences for making false patent declaration

25. A person who, when making a declaration under regulation 23(2) —

(*a*) makes any statement or furnishes any document which the person knows or has reason to believe is false in a material particular; or

(*b*) by the intentional suppression of any material fact, furnishes information which is misleading,

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Protection of confidential supporting information relating to innovative therapeutic product applications

26.—(1) Without prejudice to section 66 of the Act, where the Authority receives an innovative therapeutic product application with confidential supporting information, the Authority, during the protected period in relation to such confidential supporting information —

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

(*b*) must not use that confidential supporting information for the purpose of determining whether to grant any other application to register a therapeutic product.

(2) In this regulation and regulation 27, unless the context otherwise requires —

"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 therapeutic product application; and

(*b*) about the therapeutic product that is the subject of that application;

"innovative therapeutic product application" means an application to register a therapeutic product that refers to a substance —

(*a*) that is an ingredient in the manufacture or preparation of the therapeutic product to which the application relates; and

(*b*) that has not, before that application is received by the Authority, been referred to as an ingredient in the manufacture or preparation of any other therapeutic product in any other application to register that therapeutic product under the Act;

"protected period", in relation to confidential supporting information relating to an innovative therapeutic product application received by the Authority, means a period of 5 years after the date that application is received by the Authority.

Circumstances where protection under regulation 26 does not apply

27.—(1) Despite regulation 26, the 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 purpose of determining whether to grant any other application to register a therapeutic product —

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

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

(*b*) disclose that confidential supporting information to a Government department or statutory body for the purpose of facilitating or assisting such Government department or statutory body in carrying out its duties if, in the opinion of the Authority, the Government department or statutory body, 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, if so requested by, any one or more of the following:

(i) the World Health Organization;

(ii) the Food and Agriculture Organization of the United Nations;

(iii) any regulatory agency of a country that is a party to the Agreement establishing the World Trade Organization adopted at Marrakesh on 15 April 1994;

(iv) any Advisory Committee established under section 10 of the Act.

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

(*a*) that applicant —

(i) has notified the Authority in writing that *P* may grant that consent; and

(ii) has not notified the Authority in writing that *P*'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 *P* and the applicant or *P* has notified the Authority in writing of the transfer.

Disclosure of information on applications for registration

28. For the purposes of section 66(2)(*d*) of the Act, the Authority may from time to time disclose, for the information of the public and in the manner determined by the Authority, such particulars of applications for the registration of therapeutic products which it receives as it may determine, provided that the particulars to be disclosed under this regulation exclude —

(*a*) any trade secret; and

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

Registration exclusivity

29. Where —

(*a*) information relating to the safety or efficacy of a therapeutic product has been provided to the Authority by an applicant in support of the application for the registration of that therapeutic product; and

(*b*) the Authority has registered that therapeutic product (called the earlier registration),

the Authority may not, for a period of 5 years after the date of the earlier registration, register, on the application of any other person, a similar therapeutic product on the basis of the earlier registration, unless the registrant of the earlier registration has consented to the registration on that basis.

PART 6

DUTIES AND OBLIGATIONS OF MANUFACTURERS, IMPORTERS, ETC., OF THERAPEUTIC PRODUCTS

Division 1 — General duties

Duty to comply with enforcement requirements

30.—(1) An enforcement officer may conduct routine inspections of —

(*a*) any premises that are used for the manufacture, supply or storage of therapeutic products; and

(*b*) any conveyance that is being used for the transport of therapeutic products.

(2) An enforcement officer conducting a routine inspection under paragraph (1) may —

(*a*) require any person having possession or control of any therapeutic product that is found during the inspection to furnish, without charge, a sample of such therapeutic product for the Authority's examination; and

(*b*) take or cause to be taken any photograph of —

(i) the premises or conveyance mentioned in paragraph (1); or

(ii) any property or material found on the premises or in the conveyance.

Duty to maintain records of manufacture

31.—(1) A manufacturer of a therapeutic product, other than a healthcare institution licensee, must maintain records of —

(*a*) such information relating to the therapeutic product and its manufacture or assembly as the Authority may specify on the Authority's website or, if the manufacturer is the holder of a manufacturer's licence, in the manufacturer's licence; and

(*b*) the manufacture of each batch of the therapeutic product and of the tests carried out on each of such batch, in the

manner specified on the Authority's website or in the relevant licence issued by the Authority (if applicable).

(2) The manufacturer must maintain for any therapeutic product the records mentioned in paragraph (1) for the longer of the following periods:

(*a*) one year after the expiry date of the therapeutic product;

(*b*) 5 years after the date of manufacture of the therapeutic product.

(3) A manufacturer of a therapeutic product who fails to comply with paragraph (1) or (2) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(4) A person who, in compliance or purported compliance with paragraph (1), furnishes the Authority or an enforcement officer with any record which the person knows is false or misleading shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Duty to maintain records of receipt and supply

32.—(1) Paragraphs (2) and (3) apply to a person (*P*) who is —

(*a*) a licensee or registrant of a therapeutic product; or

(*b*) the supplier of a therapeutic product in accordance with regulation 47, 49, 51 or 58(1)(*a*), (*b*) or (*d*).

(2) *P* must —

(*a*) if *P* is not the manufacturer of the therapeutic product, maintain a record of every receipt by *P* of the therapeutic product;

(*b*) maintain a record of every supply by *P* of the therapeutic product; and

(*c*) produce for inspection by the Authority or an enforcement officer the record of every receipt or supply as and when required by the Authority or enforcement officer.

(3) *P* must ensure that every record mentioned in paragraph (2) —

(*a*) contains, in relation to each receipt by *P* of the therapeutic product, all of the following information:

(i) the proprietary name or appropriate non-proprietary name of the therapeutic product, if the therapeutic product is supplied by a manufacturer, importer or wholesaler, as the case may be;

(ii) the date on which the therapeutic product is received;

(iii) the name and address of the person from whom the therapeutic product is received;

(iv) the quantity of the therapeutic product received;

(v) the identification number (including the control number, lot number, batch number or serial number) of the therapeutic product received;

(*b*) contains, in relation to each supply by *P* of the therapeutic product, all of the following information:

(i) the proprietary name or appropriate non-proprietary name of the therapeutic product;

(ii) the date on which the therapeutic product is supplied;

(iii) the name and address of the person to whom the therapeutic product is supplied;

(iv) the quantity of the therapeutic product supplied;

(v) the identification number (including the control number, lot number, batch number or serial number) of the therapeutic product supplied; and

(*c*) is retained for at least 2 years after the date on which the therapeutic product is so supplied to another person.

(4) A person who fails to comply with paragraph (2) or (3) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(5) A person who, in compliance or purported compliance with paragraph (2) or (3), furnishes the Authority or an enforcement officer with any record which the person knows is false or misleading shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Duty to maintain records of defects and adverse effects

33.—(1) Every manufacturer, importer or registrant of a therapeutic product must —

(*a*) maintain a record of every event or other occurrence that reveals any defect in the therapeutic product or that concerns any adverse effect arising from the use of the therapeutic product; and

(*b*) produce such record for inspection by the Authority or an enforcement officer as and when required by the Authority or enforcement officer.

(2) A person mentioned in paragraph (1) must ensure that every record mentioned in that paragraph —

(*a*) contains all of the following information:

(i) the proprietary name or appropriate non-proprietary name of the therapeutic product which is defective or of which an adverse effect has arisen from its use;

(ii) the date on which the person first became aware of the event or occurrence;

(iii) the identification number or mark (including the control number, lot number, batch number or serial number) of the therapeutic product;

(iv) the nature of the defect or adverse effect;

(v) any other information that the Authority may specify in writing; and

(*b*) is retained for at least 2 years after the expiry date of the therapeutic product.

(3) A person who fails to comply with paragraph (1) or (2) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(4) A person who, in compliance or purported compliance with paragraph (1) or (2), furnishes the Authority or an enforcement officer with any record which the person knows is false or misleading shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Duty to report defects and adverse effects

34.—(1) For the purposes of section 42(1)(*a*) of the Act, every manufacturer, importer, supplier or registrant of a therapeutic product must, upon becoming aware of any defect in the therapeutic product, report the defect to the Authority —

(*a*) if the defect represents a serious threat to persons or public health, within 48 hours; or

(*b*) in all other cases, within 15 days,

after the manufacturer, importer, supplier or registrant, as the case may be, first receives notice of the defect.

(2) For the purposes of section 42(1)(*b*) of the Act, every manufacturer, importer, supplier or registrant of a therapeutic product must, upon becoming aware of any serious adverse reaction arising from the use of the therapeutic product, report the serious adverse reaction to the Authority immediately, but in any case no later than 15 days after the manufacturer, importer, supplier or registrant first becomes aware of the serious adverse reaction.

(3) In this regulation, "serious adverse reaction" means an adverse effect that is unintended and occurs in association with the use or administration of a therapeutic product at doses normally used in humans for prophylaxis, diagnosis or therapy of a disease or for the restoration, correction or modification of a physiological function, and that —

(*a*) may result in a person's death;

(*b*) may threaten a person's life;

(*c*) results in a person being hospitalised or prolongs a person's existing stay in hospital;

(*d*) results in a person's persistent or significant disability or incapacity;

(*e*) results in a congenital anomaly or birth defect; or

(*f*) is judged to be medically important even though the effect might not be immediately life-threatening or result in death or hospitalisation, but may jeopardise the person's health or may require intervention to prevent the person's death or one of the other outcomes mentioned in sub-paragraphs (*c*), (*d*) and (*e*).

Duty to notify Authority concerning recall

35.—(1) For the purposes of section 44(1) of the Act, every manufacturer, importer, supplier or registrant of a therapeutic product who intends to recall a therapeutic product must immediately, but in any case no later than 24 hours before the start of the intended recall, notify the Authority of, and the reasons for, the intended recall.

(2) The notice in paragraph (1) must be made in such form and manner as the Authority may require.

(3) Where the Authority has been notified of the intended recall of a therapeutic product under paragraph (1), the Authority may by written notice require the manufacturer, importer, supplier or registrant of the therapeutic product to do either or both of the following:

(*a*) investigate the matter occasioning the recall of the therapeutic product and provide a report of the findings of the investigation;

(*b*) take such other measures as the Authority thinks necessary.

(4) A person to whom a notice in paragraph (3) is given must comply with the notice at the person's own cost and within the time specified in the notice or, if no time is specified in the notice, within a reasonable time after the date of the notice.

(5) A person who fails to comply with paragraph (4) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Division 2 — Duties specific to licensees

Duty of licensed manufacturer

36. Without prejudice to any other provision in this Part, a holder of a manufacturer's licence for a therapeutic product —

(*a*) must ensure, and maintain objective evidence to establish, that the manufacture of the therapeutic product complies with the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme Guide to Good Manufacturing Practice for Medicinal Products;

(*b*) must provide and maintain, or ensure the provision and maintenance of, such staff, premises, equipment and facilities as are necessary for carrying out, in accordance with the holder's licence, such stages of the manufacture of the therapeutic product as are undertaken by the holder;

(*c*) must not carry out any stages of manufacture of the therapeutic product in any premises not specified in the holder's licence;

(*d*) must provide and maintain, or ensure the provision and maintenance of, such staff, premises, equipment and facilities for the handling and storage of the therapeutic product as are necessary to prevent the deterioration of the therapeutic product while it is in the holder's ownership, possession or control;

(*e*) must only use the premises specified in the holder's licence, or such other premises as may be approved from time to time by the Authority, for handling or storing the therapeutic product;

(*f*) must carry out, or arrange for a testing laboratory as specified in the licence to carry out, tests on the strength, quality and purity of the therapeutic product to ensure that

the standards of the therapeutic product comply with any applicable standard set by the Authority for the therapeutic product;

(*g*) must conduct all manufacturing operations in such a way as to ensure that the therapeutic product is of the correct identity and conforms with the applicable standards of strength, quality and purity; and

(*h*) must ensure that any tests for determining conformity with the applicable standards and specifications applying to the therapeutic product are, unless otherwise provided in the licence, applied to samples taken after all manufacturing processes have been completed, or at such earlier stage in the manufacture as may be approved by the Authority.

Duty of licensed importer

37. Without prejudice to any other provision in this Part, a holder of an importer's licence for a therapeutic product —

(*a*) must ensure, and maintain objective evidence to establish, that the handling and storage of the therapeutic product complies with any standard set out by the Authority on the Authority's website for the therapeutic product;

(*b*) must provide and maintain, or ensure the provision and maintenance of, such staff, premises, equipment and facilities for the handling and storage of the therapeutic product as are necessary to prevent the deterioration of the therapeutic product while it is in the holder's ownership, possession or control; and

(*c*) must not use, for any purpose mentioned in paragraph (*b*), any premises other than the premises specified in the holder's licence, or such other premises as may be approved from time to time by the Authority.

Duty of licensed wholesaler

38. Without prejudice to any other provision in this Part, a holder of a wholesaler's licence for a therapeutic product —

(*a*) must ensure, and maintain objective evidence to establish, that the handling, storage and distribution of the therapeutic product complies with any standard set out by the Authority on the Authority's website for the therapeutic product;

(*b*) may only supply the therapeutic product by wholesale to a person who may lawfully supply such therapeutic products in accordance with the Act;

(*c*) must provide and maintain, or ensure the provision and maintenance of, such staff, premises, equipment and facilities for the handling, storage and distribution of the therapeutic product as are necessary to prevent the deterioration of the therapeutic product while it is in the holder's ownership, possession or control; and

(*d*) must not use, for any purpose mentioned in paragraph (*c*), any premises other than the premises specified in the holder's licence, or such other premises as may be approved from time to time by the Authority.

Responsible person

39.—(1) A licensee must appoint one or more persons as a responsible person to be named as such in the licence.

(2) The licensee must ensure that —

(*a*) the responsible person has adequate knowledge of the activities to be carried out and of the procedures to be performed under the licence;

(*b*) the responsible person has relevant working experience relating to those activities and procedures;

(*c*) in the case of a manufacturer's licence, the responsible person named in the licence has practical experience in production supervision or in testing and checking to ensure the quality of therapeutic products or related health products;

(*d*) in the case of an importer's licence or wholesaler's licence for the import or supply of any therapeutic product that is not registered at the request of a qualified practitioner for

the use of the qualified practitioner's patient, the responsible person named in the licence is a qualified pharmacist or such other person as the Authority may approve;

(*e*) in the case of an importer's licence or a wholesaler's licence for the import or supply by wholesale of prescription-only medicine or pharmacy-only medicine, the responsible person named in the licence is a qualified pharmacist or such other person as the Authority may approve; and

(*f*) at any time, there is at least one responsible person who is contactable by the Authority by way of a mobile telephone number or an email address.

(3) The licensee must ensure that the responsible person discharges the duties imposed on such a person by the terms of the licence.

(4) The licensee must ensure that no person, other than the person or persons named as the responsible person in the licence, may act as the responsible person.

Offence for contravention of duties

40. A licensee who fails to comply with regulation 36, 37, 38 or 39 shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Changes affecting licence

41.—(1) Every licensee must notify the Authority of —

(*a*) any change or proposed change to any particulars furnished by the licensee to the Authority in relation to the application for the licensee's licence; and

(*b*) any change or proposed change that significantly affects the activities of the licensee that are authorised by that licence.

(2) A notice under paragraph (1) must —

(*a*) be made in such form and manner as the Authority may require;

(*b*) be submitted within such time as the Authority may specify in the conditions of the licence;

(*c*) be accompanied by such particulars, information, documents and samples as the Authority may require;

(*d*) be accompanied by the relevant fee specified in the Sixth Schedule; and

(*e*) if required by the Authority, be accompanied by a statutory declaration by the licensee verifying any information contained in or relating to the notice.

(3) A licensee must not, without the prior approval of the Authority, make any change that significantly affects the activities of the licensee that are authorised by the licensee's licence.

(4) An application for the Authority's approval under paragraph (3) must be made in the form and manner specified on the Authority's website.

(5) For the purposes of paragraphs (1) and (3), a change that significantly affects the activities of a licensee that are authorised by the licensee's licence includes a change of one or more of the following:

(*a*) the premises where the licensee operates;

(*b*) the facilities and equipment used by the licensee;

(*c*) the operations and processes carried out by the licensee;

(*d*) the responsible person mentioned in regulation 39.

(6) A licensee who fails to comply with paragraph (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(7) A licensee who —

(*a*) in compliance or purported compliance with paragraph (1), furnishes the Authority with any notice under paragraph (1) which the licensee knows is false or misleading; or

(*b*) fails to comply with paragraph (3),

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Division 3 — Duties specific to registrants

Changes concerning registered therapeutic product

42.—(1) A registrant of a registered therapeutic product must, unless the change is of a type specified on the Authority's website to be one for which the Authority's approval is not required, obtain prior approval from the Authority before effecting —

(*a*) any change to any particulars provided in relation to the registration of the therapeutic product; or

(*b*) any change that may affect the quality, safety or efficacy of the therapeutic product.

(2) An application for the Authority's approval under paragraph (1) must —

(*a*) be made in such form and manner as the Authority may require;

(*b*) be submitted within such time as the Authority may specify in the conditions of the registration of the therapeutic product;

(*c*) be accompanied by such particulars, information, documents and samples as the Authority may require;

(*d*) be accompanied by the relevant fee specified in the Sixth Schedule; and

(*e*) if required by the Authority, be accompanied by a statutory declaration by the registrant verifying any information contained in or relating to the application.

(3) Where the Authority's approval is required under paragraph (1), the registrant of the therapeutic product must ensure that no supply is made of the therapeutic product that is subject to the proposed change until after the Authority has given its approval for the change.

(4) A registrant of a therapeutic product who fails to comply with paragraph (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(5) A registrant of a therapeutic product who —

(*a*) in compliance or purported compliance with paragraph (1), furnishes the Authority with any information under paragraph (1) which the registrant knows is false or misleading; or

(*b*) fails to comply with paragraph (3),

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Information on validity of data submitted to or considered by Authority

43.—(1) A registrant of a therapeutic product must, within 15 days after receiving any information that adversely affects the validity of any data furnished by the registrant to the Authority relating to the quality, safety or efficacy of any therapeutic product to which the registrant's registration relates, inform the Authority of such information.

(2) A registrant of a therapeutic product who fails to comply with paragraph (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(3) A registrant of a therapeutic product who, in compliance or purported compliance with paragraph (1), furnishes the Authority with any information which the registrant knows is false or misleading, shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Submission of benefit-risk evaluation reports

44.—(1) The Authority may require any registrant of a therapeutic product to submit, within the timelines specified by the Authority, a benefit-risk evaluation report relating to the therapeutic product.

(2) Where the Authority has not specified any timelines within which a benefit-risk evaluation report is required to be submitted, a registrant of a therapeutic product who is required by the Authority to submit such a report must submit the report —

(*a*) for an initial period of 2 years, at intervals of 6 months commencing from either the date of registration of the therapeutic product, or its international birth date; and

(*b*) annually, for the next 3 years.

(3) A person who fails to provide a benefit-risk evaluation report —

(*a*) as required by the Authority under paragraph (1); or

(*b*) within the timelines stipulated under paragraph (2),

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(4) In paragraph (2)(*a*), "international birth date", for a therapeutic product, means the date of the first marketing approval granted to any person for the sale of the therapeutic product in any country in the world.

Duty to carry out risk management plan

45.—(1) The Authority may, for the purposes of minimising risks relating to unsafe and inefficacious use of therapeutic products, direct a registrant of a therapeutic product to implement a risk management plan which includes, but is not limited to, the following:

(*a*) producing and distributing educational material;

(*b*) producing and distributing safety information;

(*c*) performing clinical studies of the therapeutic product;

(*d*) implementing active surveillance programmes of the therapeutic product;

(*e*) implementing programmes to restrict the supply of the therapeutic product.

(2) A registrant of a registered therapeutic product who fails to comply with a direction of the Authority under paragraph (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

PART 7

EXCEPTIONS — MANUFACTURE, IMPORT AND WHOLESALE OF THERAPEUTIC PRODUCTS WITHOUT LICENCE

Division 1 — Private hospitals and medical clinics

Compounding of therapeutic products at private hospitals and medical clinics without manufacturer's licence

46.—(1) A healthcare institution licensee for a private hospital or medical clinic may compound a therapeutic product without holding a manufacturer's licence, if —

(*a*) the therapeutic product is compounded from an active ingredient or another therapeutic product;

(*b*) the final form or packaging of the compounded therapeutic product is not available or marketed for commercial supply in Singapore;

(*c*) the compounding is carried out —

(i) at the private hospital or medical clinic or, in the case of a sterile therapeutic product, at a practice setting within the private hospital or medical clinic where standards established for the operation of clean rooms and the preparation of sterile products are in place and properly documented; and

(ii) by or under the supervision of a qualified practitioner or a qualified pharmacist practising at the private hospital or medical clinic; and

(*d*) an appropriate expiry date, either in accordance with standards set out in any specified publication or supported by a stability study, accompanies the compounded therapeutic product.

(2) In addition to the requirements in paragraph (1), the therapeutic product must be compounded in accordance with the written instructions of a qualified practitioner, if —

(*a*) the therapeutic product is for the use of any patient under the care of the qualified practitioner; and

(*b*) the therapeutic product contains an active ingredient specified in Part 1 of the Second Schedule or is within any class of therapeutic products specified in Part 2 of that Schedule.

(3) Paragraph (2) does not apply if the compounding consists only of repacking for the purpose of dispensing the therapeutic product.

(4) It does not matter whether the patient mentioned in paragraph (2) is or is not a patient at the private hospital or medical clinic at which the compounding is carried out.

(5) A therapeutic product compounded under paragraph (1) at a medical clinic must not be supplied to another medical clinic or a private hospital, unless the approval of the Authority has been obtained for the supply.

(6) An application for the Authority's approval under paragraph (5) must be made in the form and manner specified on the Authority's website.

(7) For the purposes of section 45 of the Act, a healthcare institution licensee who compounds a therapeutic product under paragraph (1) must ensure that the therapeutic product is compounded in accordance with the requirements in paragraph (1)(*c*) and (*d*), and, if applicable, paragraph (2).

(8) A person who fails to comply with paragraph (7) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

(9) For the purposes of section 41 of the Act, the Authority may require a healthcare institution licensee who compounds a therapeutic product under paragraph (1) to furnish records of any stability study mentioned in paragraph (1)(*d*).

Transfer of therapeutic products between certain healthcare institutions without wholesaler's licence

47.—(1) A healthcare institution licensee (called the transferor) may, in the case of a therapeutic product compounded under regulation 46(1) at a private hospital, transfer the transferor's stock of such therapeutic product to another private hospital or a medical clinic without holding a wholesaler's licence.

(2) A transferor may, in the case of a therapeutic product compounded under regulation 46(1) at a medical clinic, transfer the transferor's stock of such therapeutic product to another medical clinic or a private hospital without holding a wholesaler's licence, if the approval of the Authority has been obtained under regulation 46(5) for the transfer.

(3) A transferor may, in the case of a therapeutic product imported by the transferor under regulation 51 or by a licensed importer under regulation 58(1)(*f*), transfer the transferor's stock of such therapeutic product to another private hospital or medical clinic without holding a wholesaler's licence.

Division 2 — Licensed retail pharmacies

Compounding of therapeutic products at licensed retail pharmacies without manufacturer's licence

48.—(1) The holder of a pharmacy licence relating to a licensed retail pharmacy may compound a therapeutic product without holding a manufacturer's licence, if —

(*a*) the therapeutic product is compounded from an active ingredient or another therapeutic product;

(*b*) the final form or packaging of the compounded therapeutic product is not available or marketed for commercial supply in Singapore;

(*c*) the compounding is carried out —

(i) at the licensed retail pharmacy;

(ii) by a qualified pharmacist or a person acting under the supervision of a qualified pharmacist;

(iii) for the purposes and under the conditions described in paragraph (2), (3) or (4), whichever is applicable; and

(iv) in the case of a sterile therapeutic product, at premises where standards established for the operation of clean rooms and the preparation of sterile products are in place and properly documented; and

(*d*) an appropriate expiry date, either in accordance with standards set out in any specified publication or supported by a stability study, accompanies the compounded therapeutic product.

(2) If the therapeutic product is to be compounded for the use of any patient under the care of a qualified practitioner and it contains an active ingredient specified in Part 1 of the Second Schedule or is within any class of therapeutic products specified in Part 2 of that Schedule, it must be compounded in accordance with —

(*a*) a valid prescription given by the qualified practitioner; or

(*b*) the written instructions of the qualified practitioner, if the qualified practitioner is practising at a private hospital or medical clinic.

(3) Paragraph (2) does not apply if the compounding consists only of repacking for the purpose of dispensing the therapeutic product.

(4) If the therapeutic product is to be compounded for the purpose of supplying for use on a ship, the therapeutic product must —

(*a*) be required to be carried on board the ship under the Merchant Shipping (Medical Stores) Regulations (Cap. 179, Rg 3), the Merchant Shipping (Maritime Labour Convention) (Medicines and Medical Equipment) Regulations 2014 (G.N. No. 181/2014) or any other written law, for the treatment of persons on board that ship; and

(*b*) be compounded in accordance with such terms and conditions as the Authority may specify in the holder's pharmacy licence.

(5) If the therapeutic product is to be compounded for the purpose of supplying for use on an aircraft, the therapeutic product must —

(*a*) form part of the medical supplies required under the Air Navigation Order (Cap. 6, O 2) or any other written law, for the treatment of persons on board the aircraft; and

(*b*) be compounded in accordance with such terms and conditions as the Authority may specify in the holder's pharmacy licence.

(6) For the purposes of section 45 of the Act, any holder of a retail pharmacy licence who compounds a therapeutic product under paragraph (1) must ensure that the therapeutic product is compounded in accordance with the requirements in paragraph (1)(*c*) and (*d*), and, if applicable, paragraph (2), (4) or (5).

(7) A person who fails to comply with paragraph (6) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

(8) For the purposes of section 41 of the Act, the Authority may require the holder of a retail pharmacy licence who compounds a therapeutic product under paragraph (1) to furnish records of any stability study mentioned in paragraph (1)(*d*).

Wholesale supply by holders of pharmacy licences without wholesaler's licence

49. The holder of a pharmacy licence may supply a therapeutic product by wholesale without holding a wholesaler's licence, if the supply —

(*a*) is to a licensed healthcare institution;

(*b*) is for use on a ship or an aircraft in accordance with the requirements in regulation 5(1)(*b*)(iv) or (v), respectively;

(*c*) is for the purpose of scientific education or research and development, or for a non-clinical purpose;

(*d*) is to a Government department or statutory board for the provision of public services;

(*e*) is between licensed retail pharmacy outlets under the same management chain; or

(*f*) consists of the supply of registered therapeutic products to companies outside Singapore for the purpose of any business or trade carried out by those companies.

Division 3 — Named patients

Re-labelling of therapeutic products without manufacturer's licence

50. Without prejudice to regulation 20, a person who imports, or supplies by wholesale, any therapeutic product that is not registered, at the request of a qualified practitioner for the use of the qualified practitioner's patient, may attach a different label to the therapeutic product without holding a manufacturer's licence.

Import of therapeutic products for patients' use without importer's licence

51.—(1) Subject to paragraph (3), a healthcare institution licensee may, without holding an importer's licence, import a therapeutic product that is not registered, if the therapeutic product is required by, and on the written instructions of, a qualified practitioner practising at the healthcare institution licensee's private hospital or medical clinic for the use of the qualified practitioner's patient.

(2) Subject to paragraph (3), the holder of a pharmacy licence may import, without holding an importer's licence, a therapeutic product that is not registered, if the therapeutic product is intended for the use by a patient of a qualified practitioner pursuant to a valid prescription given by the qualified practitioner.

(3) The Authority's prior approval must be obtained for each consignment of a therapeutic product that is imported under paragraph (1) or (2), and the amount imported must not exceed —

(*a*) a total dosage of 3 months per patient as recommended by the manufacturer of the therapeutic product; or

(*b*) such other quantity as approved by the Authority.

(4) An application for the Authority's approval under paragraph (3) must be made in the form and manner specified on the Authority's website.

Division 4 — Personal imports

Import of therapeutic products for personal use without importer's licence

52.—(1) Subject to paragraph (2), a person may, without holding an importer's licence, import for that person's personal use or for the use of any member of that person's family a therapeutic product not containing —

(*a*) any psychotropic substance; or

(*b*) an amount greater than the amount specified in the second column of the Seventh Schedule of any substance specified in the first column of that Schedule.

(2) The amount of the therapeutic product imported under paragraph (1) must not exceed a total dosage of 3 months per individual as recommended by —

(*a*) the manufacturer of the therapeutic product; or

(*b*) a foreign doctor or dentist by way of a written recommendation, or a qualified practitioner by way of a valid prescription.

Division 5 — Wholesale of therapeutic products for export

Wholesale of therapeutic products imported solely for export without wholesaler's licence

53. Without prejudice to any other provision in these Regulations, a person who holds a valid importer's licence may supply by wholesale, without a wholesaler's licence, a therapeutic product that is imported solely for the purpose of export, if the supply is in accordance with

such terms and conditions as the Authority may specify in the importer's licence.

Division 6 — Other exceptions

Import of health products by licensed manufacturer without importer's licence

54. The holder of a manufacturer's licence may import any health product without holding an importer's licence, if the health product is required for the purpose of carrying out the manufacture of a therapeutic product in accordance with the conditions of the manufacturer's licence.

Wholesale of self-manufactured therapeutic products without wholesaler's licence

55. The holder of a manufacturer's licence may supply by wholesale any therapeutic product manufactured by the holder under the manufacturer's licence without holding a wholesaler's licence, if the holder is able to provide and maintain, or ensure the provision and maintenance of, such staff, premises, equipment and facilities for the distribution of the therapeutic product as are necessary to prevent the deterioration of the therapeutic product while it is in the holder's ownership, possession or control.

Wholesale of therapeutic products to ships or aircraft without wholesaler's licence

56.—(1) A person may supply by wholesale any therapeutic product to a ship without holding a wholesaler's licence, if the therapeutic product is not registered and is imported in accordance with the requirements in regulation 5(1)(*b*)(iv).

(2) A person may supply by wholesale any therapeutic product to an aircraft without holding a wholesaler's licence, if the therapeutic product is not registered and is imported in accordance with the requirements in regulation 5(1)(*b*)(v).

Therapeutic products for research or non-clinical purposes

57.—(1) A manufacturer's licence is not required for the manufacture of a therapeutic product, if the manufacture —

(*a*) is solely for —

(i) the purpose of scientific education or research and development; or

(ii) a non-clinical purpose; and

(*b*) is not for any supply to the public.

(2) A manufacturer of a therapeutic product for any of the purposes mentioned in paragraph (1)(*a*)(i) or (ii) is not required to maintain records of manufacture in compliance with regulation 31.

(3) A person may supply a therapeutic product for any of the purposes mentioned in paragraph (1)(*a*)(i) or (ii) without holding a wholesaler's licence if there is no supply of the therapeutic product to the public.

PART 8

EXCEPTIONS — SUPPLY OF THERAPEUTIC PRODUCTS WITHOUT REGISTRATION

Prescribed exceptions

58.—(1) For the purposes of section 15(1) of the Act and without prejudice to any other provision in these Regulations, the prescribed exceptions to the prohibition in that section against the supply of a health product that is not registered, are the following:

(*a*) the supply of a therapeutic product compounded at a private hospital under regulation 46 to another private hospital;

(*b*) the supply of a therapeutic product compounded at a private hospital under regulation 46 to a patient of a qualified practitioner practising at any private hospital or medical clinic;

(*c*) the supply of a therapeutic product compounded at a medical clinic under regulation 46 to a patient of a qualified practitioner —

(i) practising at that medical clinic; or

(ii) practising at another medical clinic or a private hospital, if the Authority's approval has been obtained for the supply under regulation 46(5);

(*d*) the supply of a therapeutic product that has been compounded at a licensed retail pharmacy in accordance with, and supplied for the purposes mentioned in, regulation 48;

(*e*) the supply of a therapeutic product by a qualified practitioner to the qualified practitioner's patient;

(*f*) the supply of a therapeutic product by a licensed importer to a private hospital or medical clinic in accordance with the requirements in regulation 5(1)(*b*)(i);

(*g*) the supply by a healthcare institution licensee for a private hospital or medical clinic of a therapeutic product that is imported under regulation 51(1) to a patient of a qualified practitioner practising at the private hospital or medical clinic;

(*h*) the supply of a therapeutic product by a holder of a pharmacy licence pursuant to a valid prescription given by a qualified practitioner for the use of the qualified practitioner's patient under regulation 51(2);

(*i*) the supply of a therapeutic product by a person, who has imported the therapeutic product under regulation 52, to a member of the person's family;

(*j*) the supply of a therapeutic product for use on a ship or an aircraft in accordance with the requirements in regulation 5(1)(*b*)(iv) or (v), respectively;

(*k*) the supply of a therapeutic product for —

(i) the purpose of scientific education or research and development; or

(ii) a non-clinical purpose,

provided there is no supply of the therapeutic product to the public;

(*l*) the supply by wholesale of a therapeutic product that does not contain a psychotropic substance or is not a controlled drug and is —

(i) manufactured solely for export; or

(ii) imported solely for re-export;

(*m*) the export of any therapeutic product, subject to the approval of the Authority under regulation 8 or 9, where applicable.

(2) In paragraph (1)(*l*), "controlled drug" has the same meaning as in the Misuse of Drugs Act (Cap. 185).

Supply of therapeutic products compounded under contractual agreement with licensed manufacturer

59.—(1) Without prejudice to any other provision in these Regulations, the prohibition in section 15(1) of the Act against the supply of a health product, unless the health product is registered, does not apply to a therapeutic product that is compounded in accordance with paragraph (2) and is supplied in either of the following cases:

(*a*) by a licensed manufacturer to a private hospital or medical clinic for the use of a patient at that private hospital or medical clinic;

(*b*) by the holder of a healthcare institution licence for a private hospital or medical clinic to a patient at that private hospital or medical clinic.

(2) For the purposes of paragraph (1), the therapeutic product must be compounded —

(*a*) under an agreement between the licensed manufacturer and the holder of the healthcare institution licence for the private hospital or medical clinic;

(*b*) in accordance with the chemical composition and the written instructions of a qualified practitioner practising at the private hospital or medical clinic for the use solely by or in connection with the patient at that hospital or clinic;

(*c*) in premises approved by the Authority; and

(*d*) in accordance with the terms and conditions specified in the manufacturer's licence held by the licensed manufacturer.

(3) Paragraph (2)(*b*) does not apply to prohibit the supply of a therapeutic product that is not registered to any patient at the private hospital or medical clinic, if the requirements in paragraph (2)(*a*), (*c*) and (*d*) are satisfied and the compounding consists only of repacking for the purpose of dispensing the therapeutic product.

Previously registered therapeutic products

60. A supplier of a registered therapeutic product may continue to supply the therapeutic product, before its expiry date, by administration to a person or by retail sale, despite a cancellation of its registration and despite the prohibition in section 15(1) of the Act against the supply of a health product that is not registered, if —

(*a*) the cancellation of the registration is either made by the Authority under section 37(2) of the Act or upon the application of the registrant under section 37(3) of the Act;

(*b*) the supplier has taken possession of the therapeutic product before the cancellation of its registration; and

(*c*) the Authority does not direct a recall of the therapeutic product from the market.

PART 9

MISCELLANEOUS

Certification of therapeutic products intended for export

61.—(1) The Authority may, on the application of a person who intends to export a therapeutic product, issue to the person a certificate certifying —

(*a*) in a case where the therapeutic product is registered under the Act, that it is so registered; or

(*b*) in a case where the therapeutic product is not so registered, that it complies with such standards or requirements as may be specified in the certificate.

(2) An application for a certificate under paragraph (1) must —

(*a*) be made in the form and manner specified on the Authority's website; and

(*b*) be accompanied by the relevant fee specified in the Sixth Schedule.

Certificate of manufacturing standard of therapeutic products

62.—(1) The Authority may, on the application of a person who manufactures a therapeutic product (called the manufacturer) and on being satisfied, after completion of an assessment of conformity, that the manufacturer conforms to an applicable Good Manufacturing Practice Standard, issue a GMP Certificate to the manufacturer subject to any terms and conditions as the Authority thinks fit.

(2) Every GMP Certificate issued is valid for a period specified in the certificate, being not longer than 3 years starting on the date of commencement of the assessment mentioned in paragraph (1).

(3) An application for a GMP Certificate must —

(*a*) be made in the form and manner specified on the Authority's website; and

(*b*) be accompanied by the relevant fee specified in the Sixth Schedule.

(4) In this regulation and the Sixth Schedule —

"GMP Certificate" means a certificate issued by the Authority to certify compliance with an applicable Good Manufacturing Practice Standard;

"Good Manufacturing Practice Standard" means the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme Guide to Good

Manufacturing Practice for Medicinal Products and any other good manufacturing practice standard approved by the Authority.

Certificate of distribution standard of therapeutic products

63.—(1) The Authority may, on the application of a person who distributes a therapeutic product and on being satisfied, after completion of an assessment of conformity, that the person conforms to an applicable Good Distribution Practice Standard, issue a GDP Certificate to the person subject to any terms and conditions as the Authority thinks fit.

(2) Every GDP Certificate issued is valid for a period specified in the certificate, being not longer than 3 years starting on the date of commencement of the assessment mentioned in paragraph (1).

(3) An application for a GDP Certificate must —

(*a*) be made in the form and manner specified on the Authority's website; and

(*b*) be accompanied by the relevant fee specified in the Sixth Schedule.

(4) In this regulation and the Sixth Schedule —

"GDP Certificate" means a certificate issued by the Authority to certify compliance with an applicable Good Distribution Practice Standard;

"Good Distribution Practice Standard" means the Authority's Guidance Notes on Good Distribution Practice and any other good distribution practice standard approved by the Authority.

Other certificates or documents

64. The Authority may, on the application of any person and upon payment of the relevant fee specified in the Sixth Schedule, issue such other certificate or document to the applicant as the Authority thinks fit.

Product quality surveillances

65.—(1) The Authority may at any time conduct a product quality surveillance for the purposes of ensuring that a therapeutic product is not a non-compliant health product within the meaning of section 48(*a*) of the Act.

(2) The Authority may require a manufacturer, supplier, licensee or registrant of a therapeutic product to furnish, without charge, any number of samples of the therapeutic product for evaluation by the Authority in the product quality surveillance.

(3) A person who fails to comply with a requirement of the Authority under paragraph (2) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

Non-compliant therapeutic products

66. For the purposes of section 48(*a*)(iii) of the Act, a therapeutic product is considered as being non-compliant if it fails to comply with the product quality characteristics, specifications and labelling approved by the Authority —

(*a*) at the time of the registration of the therapeutic product; or

(*b*) under regulation 42.

Confidential information

67. For the purposes of section 66(2)(*d*) of the Act, the Authority may disclose any confidential information relating to the quality, safety or efficacy of a therapeutic product, if —

(*a*) that disclosure is, in the opinion of the Authority, necessary to protect the health or safety of members of the public; or

(*b*) that disclosure is to a Government department or statutory body in order to enable the Government department or statutory body to perform its public functions.

Fees

68.—(1) The fees specified in the Sixth Schedule are payable in respect of the matters set out in that Schedule.

(2) An application fee mentioned in the Sixth Schedule must be paid when the application is submitted to the Authority.

(3) An evaluation fee for the registration of a therapeutic product specified in the Sixth Schedule is payable upon the Authority's acceptance of the therapeutic product for evaluation after the Authority has conducted an initial screening.

(4) For the purposes of section 31(*a*) of the Act, the prescribed retention fee is set out in the Sixth Schedule and is payable on or before each anniversary of the date of registration of the therapeutic product.

(5) For the purposes of section 37(2) of the Act, the Authority may cancel the registration of a therapeutic product if the retention fee is not paid within 60 days after the anniversary of the date of the registration of the therapeutic product.

(6) The Authority may, in any particular case or class of cases, waive or refund the whole or any part of any fee payable or paid under these Regulations.

FIRST SCHEDULE

Regulation 2(1)

PSYCHOTROPIC SUBSTANCES

1. The following substances:

Allobarbital

Alprazolam

[*Deleted by S 219/2017 wef 01/05/2017*]

Aminorex

Amobarbital

Barbital

Bromazepam

Brotizolam

Butalbital

Butobarbital

FIRST SCHEDULE — *continued*

Camazepam

Cathine

Chlordiazepoxide

Clobazam

Clonazepam

Clorazepate

Clotiazepam

Cloxazolam

Cyclobarbital

Delorazepam

Diazepam

Estazolam

Ethchlorvynol

Ethinamate

Ethyl loflazepate

Etilamfetamine

Fencamfamin

Fenproporex

Fludiazepam

Flurazepam

Glutethimide

Halazepam

Haloxazolam

Ketazolam

Lefetamine

Loprazolam

Lorazepam

Lormetazepam

Mazindol

FIRST SCHEDULE — *continued*

Medazepam

Mefenorex

Meprobamate

Mesocarb

Methylphenobarbital

Methyprylon

Midazolam

Nitrazepam

Nordazepam

Oxazepam

Oxazolam

Pemoline

Pentazocine

Pentobarbital

Phenobarbital

Phentermine

Pinazepam

Prazepam

Secbutabarbital

Temazepam

Tetrazepam

Vinylbital

Zolpidem

2. The salts of the substances specified in paragraph 1, wherever the existence of such salts is possible.

3. Any preparation of a product containing one or more of the substances specified in paragraph 1 or 2.

SECOND SCHEDULE

Regulations 10(1), 46(2) and 48(2)

PART 1

ACTIVE INGREDIENTS IN PRESCRIPTION-ONLY MEDICINES

(±)-4-ethyl-2, 5-dimethoxy-α-phenethylamine (2C-E)

2-Deoxy-2-[18F] fluoro-d-glucose

2-Phenylcinchoninic acid; 2-salicylcinchoninic acid

3-Di-n-butylaminomethyl-4,5,6-trihydroxyphthalide

5-Phenylhydantoin

Abacavir

Abatacept

Abciximab

Abiraterone

Acamprosate

Acarbose

Acebutolol

Aceclofenac

Acemetacin

Acepromazine

Acetanilide; alkyl acetanilides

Acetazolamide

Acetohexamide

Acetorphine

Acetylcarbromal

Acetylcysteine

Acetyldigoxin

Acetyldihydrocodeine

Acetylmethadol

Acetylstrophanthidin

SECOND SCHEDULE — *continued*

Acipimox

Acitretin

Acrivastine

Actinomycins

Acyclovir

Adalimumab

Adapalene

Adefovir

Adicillin

Adiphenine

Adrenaline

Adrenocorticotropic hormone (ACTH)

Afatinib

Aflibercept

Agalsidase beta

Agomelatine

Alatrofloxacin

Alcaftadine

Alclofenac

Alclometasone

Alcuronium

Aldesleukin

Aldosterone

Alefacept

Alemtuzumab

Alendronic acid

Alfacalcidol

Alfentanil

Alfuzosin

SECOND SCHEDULE — *continued*

Algestone

Alglucosidase alfa

Aliskiren

Allobarbitone

Allopurinol

Allylisopropylacetylurea

Allyloestrenol

Allylprodine

Alminoprofen

Almitrine

Alogliptin

Alosetron

Alphacalcidol

Alphacetylmethadol

Alphachloralose

Alphadolone

Alphameprodine

Alphamethadol

Alphaprodine

Alphaxalone

Alprazolam

Alprenolol

Alprostadil

Alseroxylon

Alteplase

Altretamine

Amantadine

Ambenonium

Ambroxol

SECOND SCHEDULE — *continued*

Ambuside

Ambutonium

Ametazole

Amethocaine

[*Deleted by S 219/2017 wef 01/05/2017*]

Amidopyrine

Amifostine

Amikacin

Amiloride

Amineptine

Aminocaproic acid

Aminoglutethimide

Aminophylline

Aminopterin

Aminorex

Amiodarone

Amisulpride

Amitriptyline

Amlodipine

Ammonium lactate

Amoxycillin

Amphetamine

Amphomycin

Amphotericin B

Ampicillin

Amprenavir

Amrinone

Amsacrine (M-AMSA)

Amylobarbitone

SECOND SCHEDULE — *continued*

Amylocaine

Anagrelide

Anastrozole

Ancrod

Androsterone

Angiotensin amide

Anidulafungin

Anileridine

Anistreplase

Antazoline

Apixaban

Apomorphine

Apraclonidine

Apramycin

Aprepitant

Aprobarbitone

Aprotinin

Aripiprazole

Arotinolol

Arsphenamine

Arteether

Artemether

Artemisinin

Artesunate

Articaine

Asenapine

Aspoxicillin

Astemizole

Asunaprevir

SECOND SCHEDULE — *continued*

Atazanavir

Atenolol

Atomoxetine

Atorvastatin

Atosiban

Atovaquone

Atracurium

Atropine

Auranofin

Axitinib

Azacitidine

Azacyclonol

Azaperone

Azapropazone

Azasetron

Azatadine

Azathioprine

Azelaic acid

Azelastine

Azidamphenicol

Azidocillin

Azilsartan

Azithromycin

Aztreonam

Bacampicillin

Bacitracin

Baclofen

Bambermycin

Bamipine

SECOND SCHEDULE — *continued*

Barbitone

Barbituric acid

Basiliximab

Becaplermin

Beclamide

Beclomethasone

Befunolol

Bekanamycin

Belimumab

Bemegride

Benactyzine; its quarternary compounds

Benapryzine

Benazepril

Bendamustine hydrochloride

Bendrofluazide

Benethamine penicillin

Benfluorex

Benoxaprofen

Benperidol

Benserazide

Benzamidosalicylic acid

Benzathine penicillin

Benzbromarone

Benzethidine

Benzhexol

Benzilonium

Benzocaine

Benzoctamine

Benzoestrol

SECOND SCHEDULE — *continued*

Benzphetamine

Benzquinamide

Benzthiazide

Benztropine and its homologues

Benzylfentanyl

Benzylmorphine

Benzylpenicillin

Besifloxacin

Betahistine

Betameprodine

Betamethadol

Betamethasone

Betaprodine

Betaxolol

Bethanechol

Bethanidine

Betiatide

Bevacizumab

Bevonium methyl sulphate

Bezafibrate

Bezitramide

Bicalutamide

Bicisate dihydrochloride

Bifonazole

Bilastine

Bimatoprost

Biperiden

Bisoprolol

Bleomycin

SECOND SCHEDULE — *continued*

Boceprevir

Boldenone undecenoate

Bopindolol

Bortezomib

Bosentan

Botulinum toxin

Brentuximab

Bretylium

Brimonidine

Brinzolamide

Brolamfetamine

Bromazepam

Bromhexine

Bromocriptine

Bromodiphenhydramine

Bromvaletone

Brotizolam

Budesonide

Bufexamac

Buflomedil

Buformin

Bumadizone calcium

Bumetanide

Bunazosin

Buphenine hydrochloride

Bupivacaine

Bupranolol

Buprenorphine

Bupropion

SECOND SCHEDULE — *continued*

Buserelin

Buspirone

Busulphan

Butacaine

Butalbital

Butamirate

Butanilicaine

Butizide

Butobarbitone

Butoconazole

Butriptyline

Butropium bromide

Butylchloral hydrate

Cabazitaxel

Cabergoline

Cabimicina

Calcipotriol

Calcitonin

Calcitriol

Calcium barbiturate

Calcium carbimide

Calcium dobesilate

Calfactant

Camazepam

Canagliflozin

Canakinumab

Candesartan

Candicidin

Capecitabine

SECOND SCHEDULE — *continued*

Capreomycin

Captodiame

Captopril

Caramiphen

Carbachol

Carbamazepine

Carbenicillin

Carbenoxolone

Carbetocin

Carbidopa

Carbimazole

Carboplatin

Carboprost

Carbromal

Carbutamide

Carfecillin

Carfentanil

Carisoprodol

Carmustine

Carperidine

Carprofen

Carteolol

Carvedilol

Caspofungin

Cathine

Cathinone

Cefaclor

Cefadroxil

Cefamandole

SECOND SCHEDULE — *continued*

Cefatrizine

Cefdinir

Cefepime

Cefixime

Cefodizime

Cefoperazone

Cefotaxime

Cefotiam

Cefoxitin

Cefpirome

Cefprozil

Cefsulodin

Ceftaroline

Ceftazidime

Ceftibuten

Ceftizoxime

Ceftriaxone

Cefuroxime

Celecoxib

Cephalexin

Cephaloglycin

Cephaloram

Cephaloridine

Cephalothin

Cephazolin

Cephradine

Ceritinib

Cerivastatin

Certolizumab

SECOND SCHEDULE — *continued*

Cetrorelix

Cetuximab

Chenodeoxycholic acid

Chloral hydrate

Chlorambucil

Chloramphenicol

Chlorcyclizine

Chlordiazepoxide

Chlormadinone

Chlormerodrin

Chlormethiazole

Chlormezanone

Chlormidazole

Chlorothiazide

Chloroquine

Chlorpheniramine

Chlorphenoxamine

Chlorphentermine

Chlorpromazine

Chlorpropamide

Chlorprothixene and other derivatives of 9-methylenethiazanthene

Chlorquinaldol

Chlortetracycline

Chlorthalidone and other derivatives of o-chlorobenzene sulphonamide

Chlorzoxazone

Cholestyramine

Choline Theophyllinate

Chorionic gonadotrophin

Chromium [51CR] Edetate

SECOND SCHEDULE — *continued*

Chromomycin A

Ciclacillin

Ciclesonide

Ciclopirox

Cilastatin

Cilazapril

Cilostazol

Cimetidine

Cinacalcet

Cinchocaine

Ciprofibrate

Ciprofloxacin

Cisapride

Cisatracurium

Cisplatin

Citalopram

Citicoline

Cladribine

Clarithromycin

Clavulanic acid

Clebopride

Clemastine

Clemizole

Clenbuterol

Clidinium

Clindamycin

Clioquinol

Clobazam

Clobenzorex

SECOND SCHEDULE — *continued*

Clobetasol

Clobetasone

Clobutinol

Clodronic acid

Clofarabine

Clofazimine

Clofedanol

Clofibrate

Clomiphene

Clomipramine

Clomocycline

Clonazepam

Clonidine

Clonitazene

Clopamide

Clopenthixol

Clopidogrel

Cloprostenol

Clorazepate

Clorexolone

Clorprenaline

Clostebol

Clostridiopeptidase A

Clotiazepam

Clotrimazole

Cloxacillin

Cloxacillin benzathine

Cloxazolam

Cloxiquine

SECOND SCHEDULE — *continued*

Clozapine

Cobicistat

Codeine

Co-dergocrine mesylate

Colchicine

Colestipol

Colimycin

Colistin

Corifollitropin alfa

Corticorelin

Cortisone

Crisantaspase

Crizotinib

Cropropamide

Crotethamide

Cyclandelate

Cyclarbamate

Cyclizine

Cyclobarbitone

Cyclofenil

Cyclopenthiazide

Cyclopentolate

Cyclophosphamide

Cycloserine

Cyclosporin

Cyclothiazide

Cycrimine

Cyproheptadine

Cyproterone

SECOND SCHEDULE — *continued*

Cytarabine

Dabigatran etexilate mesylate

Dabrafenib

Dacarbazine

Daclatasvir

Daclizumab

Dactinomycin

Dalfopristin

Dalteparin

Danazol

Danthron

Dantrolene

Dapagliflozin

Dapoxetine

Dapsone

Daptomycin

Darbepoetin alfa

Darunavir

Dasabuvir

Dasatinib

Daunorubicin

Debrisoquine

Deferasirox

Deferiprone

Deferoxamine

Degarelix

Dehydroemetine

Dehydroepiandrosterone (DHEA)

Delapril

SECOND SCHEDULE — *continued*

Delmadinone

Delorazepam

Demecarium

Demeclocycline

Demoxytocin

Denosumab

Deoxycortone

Deptropine

Deserpidine

Desferrioxamine mesylate

Desfluorotriamcinolone

Desflurane

Desipramine

Deslanoside

Desloratadine

Desmopressin

Desogestrel

Desomorphine

Desonide

Desoxymethasone

Desvenlafaxine

Dexamethasone

Dexamphetamine

Dexetimide

Dexfenfluramine

Dexketoprofen

Dexlansoprazole

Dexmedetomidine

Dexrazoxane

SECOND SCHEDULE — *continued*

Dextromethorphan

Dextromoramide

Dextropropoxyphene

Dextrorphan

Dextrothyroxine sodium

Diacetylmorphine

Diacetylnalorphine

Diamorphine

Diampromide

Diazepam

Diazoxide

Dibekacin

Dibenzepin

Dibucaine

Dichloralphenazone

Dichlorophenarsine

Dichlorphenamide

Diclofenac

Dicloxacillin

Didanosine

Dienoestrol

Dienogest

Diethanolamine fusidate

Diethylcarbamazine

Diethylthiambutene

Difenoxin

Diflucortolone

Diflunisal

Digoxin

SECOND SCHEDULE — *continued*

Dihydralazine

Dihydroartemisin

Dihydrocodeine

Dihydrocodeinone

Dihydroergotamine

Dihydroergotoxine

Dihydroetorphine

Dihydromorphine

Dihydrostreptomycin

Diloxanide

Diltiazem

Dimenhydrinate

Dimercaprol

Dimethindene

Dimethisoquin

Dimethisterone

Dimethothiazine

Dimethoxanate

Dimethpyrindene

Dimethyl 4-sulphamoylphenyl phosphorothioate

Dimethyl sulphoxide

Dimethylthiambutene

Dimethyltubocurarine

Dinitronaphthols

Dinitrothymols

Dinoprost

Dinoprostone

Dioxaphetyl butyrate

Diperodon

SECOND SCHEDULE — *continued*

Diphenidol

Diphenylpyraline

Dipipanone

Dipivefrin

Diprophylline

Dipyridamole

Dipyrone

Dirithromycin

Disopyramide

Distigmine

Disulfiram

Disulphamide

Dithienylallylamines; dithienyl-alkylallylamines

Dobutamine

Docetaxel

Dolutegravir

Domperidone

Donepezil

Dopamine

Doripenem

Dorzolamide

Dothiepin

Doxapram

Doxazosin

Doxepin

Doxofylline

Doxorubicin

Doxycycline

Doxylamine

SECOND SCHEDULE — *continued*

Dronedarone

Droperidol

Drospirenone

Drostanolone

Drotebanol

Drotrecogin alfa

Duloxetine

Dutasteride

Dydrogesterone

Dyflos

Ebastine

Econazole

Ecothiopate iodide

Ectylurea

Eculizumab

Edoxudine

Edrophonium

Efalizumab

Efavirenz

Eletriptan

Eltrombopag olamine

Elvitegravir

Embramine

Embutramide

Emedastine

Emepronium

Emtricitabine

Emylcamate

Enalapril

SECOND SCHEDULE — *continued*

Enalaprilat

Encainide

Enflurane

Enfuvirtide

Enoxaparin

Entacapone

Entecavir

Enzalutamide

Eperisone

Ephedrine; its optical isomers

Epicillin

Epimestrol

Epinastine

Epioestriol

Epirubicin

Epithiazide

Eplerenone

Epoetin alfa

Epoetin beta

Epoprostenol

Eprosartan

Eptacog alfa

Eptifibatide

Erdosteine

Ergometrine

Ergotamine

Ergotoxine

Eribulin mesylate

Erlotinib

SECOND SCHEDULE — *continued*

Ertapenem

Erythrityl tetranitrate

Erythromycin

Erythropoietin

Escitalopram

Esmolol

Esomeprazole

Estazolam

Estramustine

Etafedrine

Etanercept

Ethacrynic acid

Ethambutol

Ethamivan

Ethamsylate

Ethchlorvynol

Ethebenecid

Ethiazide

Ethinamate

Ethinyloestradiol

Ethionamide

Ethisterone

Ethoglucid

Ethoheptazine

Ethopropazine

Ethosuximide

Ethotoin

Ethyl biscoumacetate

Ethyl loflazepate

SECOND SCHEDULE — *continued*

Ethyl p-piperidinoacetylaminobenzoate

Ethylacetanilide

Ethylmorphine

Ethylnoradrenaline

Ethyloestrenol

Ethylstibamine

Ethynodiol

Etidronic acid

Etilamfetamine

Etodolac

Etofenamate

Etofibrate

Etofylline clofibrate

Etomidate

Etonitazene

Etonogestrel

Etoposide

Etoricoxib

Etorphine

Etoxeridine

Etravirine

Etretinate

Everolimus

Exametazime

Exemestane

Exenatide

Ezetimibe

Famciclovir

Famotidine

SECOND SCHEDULE — *continued*

Fampridine

Famprofazone

Fazadinium

Febuxostat

Felbinac

Felodipine

Felypressin

Fencamfamin

Fenclofenac

Fenetylline

Fenfluramine

Fenofibrate

Fenoprofen

Fenoterol

Fenoverine

Fenpipramide

Fenpiprane

Fenproporex

Fentanyl

Fenticonazole

Feprazone

Ferric carboxymaltose

Ferucarbotran

Fexofenadine

Filgrastim

Finasteride

Fingolimod

Flavomycin

Flavoxate

SECOND SCHEDULE — *continued*

Flecainide

Flibanserin

Floxuridine

Fluanisone

Fluclorolone

Flucloxacillin

Fluconazole

Flucytosine

Fludarabine phosphate

Fludiazepam

Fludrocortisone

Flufenamic acid

Flugestone

Flumazenil

Flumedroxone

Flumethasone

Flumethiazide

Flunisolide

Flunitrazepam

Fluocinolone

Fluocinonide

Fluocortolone

Fluopromazine

Fluoro-2-deoxy-d-glucose

Fluoroacetamide

Fluoroacetanilide

Fluorometholone

Fluorouracil

Fluothane

SECOND SCHEDULE — *continued*

Fluoxetine

Fluoxymesterone

Flupenthixol

Fluperolone

Fluphenazine

Fluprednidene

Fluprednisolone

Fluprostenol

Flurandrenolone

Flurazepam

Flurbiprofen

Fluspirilene

Flutamide

Fluticasone

Fluvastatin

Fluvoxamine

Follicle stimulating hormone (FSH)

Follitropin alfa

Fondaparinux

Formestane

Formosulphathiazole

Formoterol

Fosamprenavir

Fosaprepitant dimeglumine

Foscarnet

Fosfestrol

Fosfomycin

Fosinopril

Fotemustine

SECOND SCHEDULE — *continued*

Framycetin

Frusemide

Ftorafur

Fulvestrant

Fumagillin

Furaltadone

Furazolidone

Furethidine

Fusafungine

Fusidic acid

Gabapentin

Gadobenate dimeglumine

Gadobutrol

Gadodiamide

Gadopentetic acid

Gadoteric acid

Gadoversetamide

Gadoxetate

Gadoxetic acid

Galantamine

Gallamine

Gallium

Ganciclovir

Ganirelix

Gatifloxacin

Gefitinib

Gemcitabine

Gemeprost

Gemfibrozil

SECOND SCHEDULE — *continued*

Gemtuzumab ozogamicin

Gentamicin

Gestodene

Gestrinone

Gestronol

Gimeracil

Glafenine

Glibenclamide

Glibornuride

Gliclazide

Glimepiride

Glipizide

Gliquidone

Glucagon

Glutethimide

Glyceryl trinitrate

Glycopyrrolate

Glycopyrronium

Glymidine

Golimumab

Gonadorelin

Goserelin

Gramicidins

Granisetron

Grepafloxacin

Griseofulvin

Guanethidine

Guanoclor

Guanoxan

SECOND SCHEDULE — *continued*

Hachimycin

Halazepam

Halcinonide

Halofantrine

Halometasone

Haloperidol and other 4-substituted derivatives of N-(3-p-fluorobenzoylpropyl) piperidine

Haloprogin

Halothane

Haloxazolam

Heparin

Heparin calcium

Heptabarbitone

Heptaminol

Hexamethonium

Hexamethylmelamine

Hexapropymate

Hexobarbitone

Hexoestrol

Histrelin

Histrelin acetate

Homatropine

Homochlorcyclizine

Hydralazine

Hydrochlorothiazide

Hydrocodone

Hydrocortisone

Hydromorphinol

Hydromorphone

SECOND SCHEDULE — *continued*

Hydroquinone

Hydroxychloroquine

Hydroxycinchoninic

Hydroxyprogesterone

Hydroxyquinoline

Hydroxyurea

Hydroxyzine

Hygromycin B

Hyoscine

Ibacitabine

Ibandronic acid

Ibrutinib

Ibuprofen

Idarubicin

Idelalisib

Idoxuridine

Idrocilamide

Idursulfase

Ifenprodil

Ifosfamide

Iloprost

Imatinib

Imidapril

Imiglucerase

Imipenem

Imipramine

Imiquimod

Indacaterol

Indapamide

SECOND SCHEDULE — *continued*

Indinavir

Indium pentetreotide

Indobufen

Indomethacin

Infliximab

Interferons

Iodixanol

Iodine-131

Ipilimumab

Ipratropium

Iprindole

Iproniazid

Irbesartan

Irinotecan

Isepamicin

Isoaminile

Isocarboxazid

Isoconazole

Isoetharine

Isoflurane

Isomethadone (isoamidone)

Isoniazid

Isoprenaline

Isopropamide

Isopyrin

Isosorbide

Isothipendyl

Isotretinoin

Isoxicam

SECOND SCHEDULE — *continued*

Isoxsuprine

Isradipine

Itopride

Itraconazole

Ivabradine

Ivermectin

Ixabepilone

Kanamycin

Kanendomycin

Ketamine

Ketanserin

Ketazolam

Ketobemidone

Ketoconazole

Ketoprofen

Ketorolac

Ketotifen

Labetalol

Lacidipine

Lacosamide

Lafutidine

Lamivudine

Lamotrigine

Lanreotide

Lansoprazole

Lanthanum carbonate hydrate

Lapatinib

Laronidase

Laropiprant

SECOND SCHEDULE — *continued*

L-Asparaginase

Latanoprost

Laudexium

Ledipasvir

Lefetamine

Leflunomide

Lenalidomide

Lenograstim

Lepirudin

Lercanidipine

Letrozole

Leucovorin

Leuprorelin

Levamisole

Levamphetamine

Levetiracetam

Levobunolol

Levocabastine

Levocetirizine

Levodopa

Levofloxacin

Levomethamphetamine

Levomethorphan

Levomoramide

Levonorgestrel

Levorphanol

Levosimendan

Levothyroxine

Lidoflazine

SECOND SCHEDULE — *continued*

Lignocaine

Linagliptin

Lincomycin

Linezolid

Liothyronine sodium

Liraglutide

Lisinopril

Lisuride

Lithium carbonate

Lixisenatide

Lodoxamide

Lofentanil

Lofepramine

Lomefloxacin

Lomustine

Lonazolac

Lopinavir

Loprazolam

Loracarbef

Lorazepam

Lormetazepam

Losartan

Loteprednol

Lovastatin

Loxoprofen

L-Pyroglutamyl-L-histidyl-L-proline amide

Lumefantrine

Luteinising hormone

Lutropin alfa

SECOND SCHEDULE — *continued*

Lymecycline

Lynoestrenol

Lypressin

Lysuride

Macitentan

Mafenide

Mangafodipir

Mannitol hexanitrate

Mannomustine

Maprotiline

Maraviroc

Mazindol

Mebanazine

Mebezonium

Mebhydrolin

Mebutamate

Mecamylamine

Meclastine

Meclofenamic acid

Meclofenoxate

Mecloqualone

Meclozine

Medazepam

Medigoxin

Medrogestone

Medroxyprogesterone

Mefenamic acid

Mefenorex

Mefloquine

SECOND SCHEDULE — *continued*

Mefruside

Megestrol

Meglumine gadoterate

Melengestrol

Melitracen

Meloxicam

Melphalan

Memantine

Menotrophin

Mepenzolate

Mephenesin

Mephentermine

Mepivacaine

Meprobamate

Mepyramine

Mequitazine

Mercaptopurine; derivatives of mercaptopurine

Meropenem

Mesalazine

MESNA (2-mercaptoethane sulfonate sodium)

Mesocarb

Mesoridazine

Mestanolone

Mesterolone

Mestranol

Metabutethamine

Metaiodobenzylguanidine (I-131)

Metaraminol

Metaxalone

SECOND SCHEDULE — *continued*

Metazocine

Metergoline

Metformin

Methacycline

Methadone (amidone)

Methadyl acetate

Methallenoestril

Methandienone

Methandriol

Methanthelinium bromide

Methapyrilene

Methaqualone

Metharbitone

Methdilazine

Methenolone

Methicillin

Methimazole

Methisoprinol

Methixene

Methocarbamol

Methohexitone

Methoin

Methoserpidine

Methotrexate

Methotrimeprazine

Methoxamine

Methoxsalen

Methoxyflurane

Methoxyphenamine

SECOND SCHEDULE — *continued*

Methsuximide

Methyclothiazide

Methyl 5-aminolevulinate hydrochloride

Methylaminoheptane

Methylamphetamine

Methyldihydromorphine

Methyldopa

Methyldopate

Methylephedrine

Methylergometrine

Methylnaltrexone bromide

Methylpentynol

Methylphenidate

Methylphenobarbitone

Methylprednisolone

Methylsulphonal

Methyltestosterone

Methylthiouracil

Methyprylone

Methysergide

Metipranolol

Metoclopramide

Metolazone

Metomidate

Metopon

Metoprolol

Metronidazole

Mexiletine

Mianserin

SECOND SCHEDULE — *continued*

Mibefradil

Micafungin

Miconazole

Micronomicin

Midazolam

Midecamycin

Midodrine

Miglitol

Milrinone

Miltefosine

Minaprine

Minocycline

Minoxidil

Mirabegron

Mirtazapine

Misoprostol

Mithramycin

Mitobronitol

Mitomycins

Mitopodozide

Mitotane

Mitoxantrone

Mivacurium

Mizolastine

m-Nitrophenol; o-Nitrophenol; p-Nitrophenol

Moclobemide

Moexipril

Molgramostim

Molindone

SECOND SCHEDULE — *continued*

Mometasone

Monofluoroacetic acid

Montelukast

Morazone

Morinamide

Moroctocog alfa

Moroxydine

Morphine methylbromide; morphine N-oxide and other pentavalent nitrogen morphine derivatives

Moxalactam

Moxifloxacin

Moxonidine

Mupirocin

Muromonab-CD3

Mustine and any other N-substituted derivatives of di-(2-chloroethyl) amine

Mycophenolic acid

Myrophine

Myrtecaine

Nabumetone

N-Acetylaspartyl glutamic acid sodium salt

Nadolol

Nadroparin

Nafarelin

Nafcillin

Naftidrofuryl

Naftifine

Nalbuphine

Nalidixic acid

Nalmefene

SECOND SCHEDULE — *continued*

Nalorphine

Naloxone

Naltrexone

Nandrolone

Naproxen

Naratriptan

Natalizumab

Natamycin

Nateglinide

N-Benzoyl sulphanilamide

Nealbarbitone

Nebivolol

Nedocromil

Nefazodone

Nefopam

Nelfinavir

Neoarsphenamine

Neomycin

Neostigmine

Nepafenac

Netilmicin

Nevirapine

Nialamide

Niaprazine

Nicardipine

Nicergoline

Nicocodine

Nicodicodine

Nicomorphine

SECOND SCHEDULE — *continued*

Nicotinic acid

Nicoumalone

Nifedipine

Nifuroxazide

Nifurzide

Nikethamide

Nilotinib

Nilvadipine

Nimesulide

Nimetazepam

Nimodipine

Nimorazole

Nintedanib

Niridazole

Nisoldipine

Nitrazepam

Nitrendipine

Nitric oxide

Nitrofurantoin

Nitrofurazone

Nitromin

Nitroprusside

Nitroxoline

Nizatidine

Nomegestrol

Nometasone

Nomifensine

Nonacog alfa

Noracymethadol

SECOND SCHEDULE — *continued*

Noradrenaline

Noramidopyrine

Norbuprenorphine

Norcodeine

Nordazepam

Norelgestromin

Norethandrolone

Norethisterone

Norethynodrel

Norfloxacin

Norgestimate

Norgestrel

Norketamine

Norlevorphanol

Normethadone

Normorphine

Norpipanone

Nortriptyline

Novobiocin

Noxythiolin

Nystatin

Obinutuzumab

Ocriplasmin

Octacosactrin

Octocog alfa

Octreotide

Oestradiol

Oestriol

Oestrone

SECOND SCHEDULE — *continued*

Ofatumumab

Ofloxacin

Olanzapine

Oleandomycin

Olmesartan

Olodaterol

Olopatadine

Olsalazine

Omalizumab

Ombitasvir

Omeprazole

Ondansetron

Opipramol

Orciprenaline

Orlistat

Ornidazole

Orphenadrine

Orthocaine

Oseltamivir

Oteracil

Oxaliplatin

Oxamniquine

Oxandrolone

Oxantel

Oxatomide

Oxazepam

Oxazolam

Oxcarbazepine

Oxedrine

SECOND SCHEDULE — *continued*

Oxidronic acid

Oxiracetam

Oxolinic acid

Oxomemazine

Oxophenarsine

Oxpentifylline

Oxprenolol

Oxybuprocaine

Oxybutynin

Oxycodone

Oxymesterone

Oxymetazoline

Oxymetholone

Oxymorphone

Oxypertine

Oxyphenbutazone

Oxyphencyclimine

Oxyphenonium

Oxytetracycline

Oxytocin

p-Aminobenzoic acid

Paclitaxel

Paliperidone

Palivizumab

Palonosetron

Pamidronate

p-Aminobenzene-sulphonamide

Pancuronium

Panitumumab

SECOND SCHEDULE — *continued*

Pantoprazole

Paraldehyde

Paramethadione

Paramethasone

Parecoxib

Pargyline

Paricalcitol

Paritaprevir

Parnaparin

Paromomycin

Paroxetine

Pasireotide

Pazopanib

Pecilocin

Pefloxacin

Pegaptanib

Pegfilgrastim

Peginterferon

Pegvisomant

Pembrolizumab

Pemetrexed

Pemoline

Pempidine

Penamecillin

Penciclovir

Penethamate

Penfluridol

Penicillamine

Penicillin G; benzylpenicillin

SECOND SCHEDULE — *continued*

Penicillin V; phenoxymethylpenicillin

Pentaerythritol tetranitrate

Pentamidine

Pentazocine

Penthienate

Pentobarbitone

Pentolinium

Pentoxifylline

Perampanel

Perfluoropropane

Pergolide

Perhexiline

Pericyazine

Perindopril

Perphenazine

Pertuzumab

Pethidine

Pethidinic acid

Phenacaine

Phenacemide

Phenacetin

Phenaglycodol

Phenazocine

Phenbenicillin

Phenbutrazate

Phencyclidine

Phendimetrazine

Phenelzine

SECOND SCHEDULE — *continued*

Phenethicillin

Phenethylamine

Phenetidylphenacetin

Pheneturide

Phenformin

Phenglutarimide

Phenindamine

Phenindione

Pheniramine

Phenmetrazine

Phenobarbitone

Phenoperidine

Phenothiazine

Phenoxybenzamine

Phenoxypropazine

Phenprocoumon

Phensuximide

Phentermine

Phentolamine

Phenylbutazone

Phenylmethyl barbituric acid

Phenylpropanolamine

Phenytoin

Phthalylsulphacetamide

Phthalylsulphathiazole

Physostigmine

Picrotoxin

Pilocarpine

Pimecrolimus

SECOND SCHEDULE — *continued*

Piminodine

Pimozide

Pinazepam

Pioglitazone

Pipecuronium

Pipemidic acid

Pipenzolate

Piperacillin

Piperazine oestrone sulphate

Piperidolate

Pipothiazine

Pipradrol

Piracetam

Pirenoxine

Pirenzepine

Piribedil

Piritramide

Piroxicam

Pirprofen

Pivmecillinam

Pizotifen

Plerixafor

Poldine methylsulphate

Polidexide

Polymethylene-bistrimethylammonium salts

Polymyxins

Polyoestradiol

Polythiazide

Pomalidomide

SECOND SCHEDULE — *continued*

Posaconazole

Practolol

Pralatrexate

Pralidoxime

Pramipexole

Prasugrel

Pravastatin

Prazepam

Praziquantel

Prazosin

Prednicarbate

Prednisolone

Prednisone

Pregabalin

Prenoxdiazine

Prenylamine

Prilocaine

Procaine

Primaquine

Primidone

Prindolol

Probenecid

Probucol

Procainamide

Procaine penicillin

Procarbazine

Prochlorperazine

Procyclidine

Profenone

SECOND SCHEDULE — *continued*

Progesterone

Proguanil

Prolintane

Promazine

Promestriene

Promethazine

Promoxolane

Pronethalol

Propafenone

Propanidid

Propantheline

Proparacaine

Propicillin

Propiomazine

Propiram

Propiverine

Propofol

Propoxyphene

Propranolol

Propylhexedrine

Propylthiouracil

Propyromazine

Proquamezine

Proquazone

Prostaglandins

Protamine sulphate

Prothionamide

Prothipendyl

Protirelin

SECOND SCHEDULE — *continued*

Protriptyline

Proxymetacaine

Proxyphylline

Prucalopride

Pyrathiazine

Pyrazinamide

Pyridinolcarbamate

Pyridostigmine

Pyrimethamine

Pyritinol

Pyrovalerone

Pyrrobutamine

Quetiapine

Quinagolide

Quinalbarbitone

Quinapril

Quinestradol

Quinestrol

Quinethazone

Quinidine

Quinine

Quinupristin

Rabeprazole

Racecadotril

Racemethorphan

Racemoramide

Racemorphan

Radium-223 chloride

Rafoxanide

SECOND SCHEDULE — *continued*

Raloxifene

Raltegravir

Raltitrexed

Ramipril

Ranibizumab

Ranitidine

Ranolazine

Rasburicase

Raubasine

Razoxane

Reboxetine

Regorafenib

Remifentanil

Repaglinide

Reserpine

Retapamulin

Reteplase

Retigabine

Retinoic acid

Reviparin

Rhodamine B

Ribavirin

Rifamide

Rifampicin

Rifaximin

Rilmenidine

Rilpivirine

Riluzole

Rimexolone

SECOND SCHEDULE — *continued*

Rimiterol

Riociguat

Risedronic acid

Risperidone

Ristocetin

Ritodrine

Ritonavir

Rituximab

Rivaroxaban

Rivastigmine

Rizatriptan

Rocuronium

Rofecoxib

Rolitetracycline

Romiplostim

Ropinirole

Ropivacaine

Rosiglitazone

Rosoxacin

Rosuvastatin

Rotigotine

Roxatidine

Roxithromycin

Rupatadine

Ruxolitinib

Sacubitril

Salazosulphadimidine

Salbutamol

Salmefamol

SECOND SCHEDULE — *continued*

Salmeterol

Santonin

Saquinavir

Saxagliptin

Secbutobarbitone

Secnidazole

Secobarbital

Secukinumab

Selegiline

Sermorelin

Sertaconazole

Sertraline

Sevelamer

Sevoflurane

Sibutramine

Sildenafil

Siltuximab

Silver sulphadiazine

Simfibrate

Simvastatin

Sirolimus

Sisomicin

Sitagliptin

Sodium apolate

Sodium aurothiomalate

Sodium dihydroazapentacene

Sodium fluoride

Sodium iodide [I-131]

Sodium molybdate

SECOND SCHEDULE — *continued*

Sodium oxidronate

Sodium pertechnetate

Sodium picosulphate

Sodium tetradecyl sulphate

Sodium valproate

Sofosbuvir

Solifenacin

Somatostatin

Somatropin

Sorafenib

Sotalol

Sparfloxacin

Spectinomycin

Spiramycin

Spironolactone

Stanolone

Stanozolol

Stavudine

Stilboestrol

Streptokinase

Streptomycin and its derivatives

Streptozocin

Strontium [89Sr]

Styramate

Succinylsulphathiazole

Sucroferric oxyhydroxide

Sufentanil

Sugammadex

Sulbactam

SECOND SCHEDULE — *continued*

Sulbenicillin

Sulfabenzamide

Sulfacytine

Sulfametopyrazine

Sulfametrole

Sulindac

Sulphabromomethazine

Sulphacetamide

Sulphachlorpyridazine

Sulphadiazine

Sulphadicramide

Sulphadimethoxine

Sulphadimidine

Sulphadoxine

Sulphaethidole

Sulphafurazole

Sulphaguanidine

Sulphaloxic acid

Sulphamerazine

Sulphamethazine

Sulphamethizole

Sulphamethoxazole

Sulphamethoxydiazine

Sulphamethoxypyridazine

Sulphametopyrazine

Sulphamonomethoxine

Sulphamoxole

Sulphanilamide

Sulphaphenazole

SECOND SCHEDULE — *continued*

Sulphapyrazole

Sulphapyridine

Sulphaquinoxaline

Sulphasalazine

Sulphasomidine

Sulphathiazole

Sulphathiourea

Sulphatolamide

Sulphaurea

Sulphinpyrazone

Sulphomyxin

Sulphonal; alkyl sulphonals

Sulpiride

Sulprostone

Sultamicillin

Sulthiame

Sumatriptan

Sunitinib

Suprofen

Suxamethonium

Suxethonium bromide

Syrosingopine

Tacrine

Tacrolimus

Tadalafil

Tafluprost

Talampicillin

Tamoxifen

Tamsulosin

SECOND SCHEDULE — *continued*

Tapentadol

Tazarotene

Tazobactam

Teclothiazide

Tedizolid

Tegafur

Tegaserod

Teicoplanin

Telbivudine

Telithromycin

Telmisartan

Temazepam

Temozolomide

Temsirolimus

Tenecteplase

Teniposide

Tenofovir

Tenonitrozole

Tenoxicam

Terazosin

Terbinafine

Terbutaline

Terconazole

Terfenadine

Teriflunomide

Teriparatide

Terlipressin

Tertatolol

Testosterone

SECOND SCHEDULE — *continued*

Tetrabenazine

Tetracaine

Tetracosactide

Tetracyclines

Tetrahydrocannabinol

Tetrazepam

Tetrofosmin

Thalidomide

Thallium

Thebacon

Thenalidine

Thenyldiamine

Theofibrate

Theophylline

Thiabendazole

Thiacetazone

Thialbarbitone

Thiamazole

Thiambutosine

Thiamphenicol

Thiazinamium methylsulphate

Thiethylperazine

Thiocarlide

Thioguanine

Thiopentone

Thiopropazate

Thioproperazine

Thioridazine

Thiotepa

SECOND SCHEDULE — *continued*

Thiothixene

Thiouracil; its alkyl derivatives

Thymalfasin

Thymoxamine

Thyroid gland, the active principles of

Thyrotrophin

Thyroxine

Tiagabine

Tianeptine

Tiapride

Tiaprofenic acid

Tibolone

Ticagrelor

Ticarcillin

Ticlopidine

Tiemonium

Tigecycline

Tigloidine

Tilidine

Tiludronic acid

Timepidium

Timolol

Tinidazole

Tinzaparin

Tioconazole

Tiotropium

Tirilazad

Tirofiban

Tixocortol

SECOND SCHEDULE — *continued*

Tizanidine

Tobramycin

Tocainide

Tocilizumab

Tofacitinib

Tofenacin

Tolazamide

Tolazoline

Tolbutamide

Tolcapone

Tolmetin

Toloxatone

Tolperisone

Tolpropamine

Tolterodine

Topiramate

Topotecan

Toremifene

Tosufloxacin

Trabectedin

Tramadol

Tranexamic acid

Tranylcypromine

Trastuzumab

Travoprost

Trazodone

Treosulphan

Tretamine

Tretinoin

SECOND SCHEDULE — *continued*

Triacetyloleandomycin

Triamcinolone

Triamterene

Triaziquone

Triazolam

Tribenoside

Tribromethyl alcohol

Trichomycin

Triclofos sodium

Tricyclamol

Trienbolone

Trientine

Trifluoperazine

Trifluorothymidine

Trifluperidol

Trifluridine

Triflusal

Trihexyphenidyl

Trimebutine

Trimegestone

Trimeperidine

Trimeprazine

Trimetaphan

Trimetazidine

Trimethoprim

Trimetrexate

Trimipramine

Trimustine

Tripamide

SECOND SCHEDULE — *continued*

Tripelennamine

Triptorelin

Tromantadine

Tropicamide

Tropisetron

Trospium

Trovafloxacin

Troxidone

Tubocurarine

Tybamate

Tylosin

Ulipristal

Umeclidinium

Unoprostone

Uramustine

Urapidil

Urea

Ureamycin

Urethane

Urokinase

Ursodeoxycholic acid

Ustekinumab

Valaciclovir

Valdecoxib

Valganciclovir

Valproic acid

Valsartan

Vancomycin

Vardenafil

SECOND SCHEDULE — *continued*

Varenicline

Vasopressin

Vecuronium

Vedolizumab

Vemurafenib

Venlafaxine

Verapamil

Vernakalant

Verteporfin

Vidarabine

Vigabatrin

Vildagliptin

Viloxazine

Vinbarbitone

Vinblastine

Vincristine

Vindesine

Vinflunine

Vinorelbine

Vinpocetine

Vinylbital

Viomycin

Virginiamycin

Vismodegib

Voriconazole

Vortioxetine

Warfarin

Xamoterol

Xipamide

SECOND SCHEDULE — *continued*

Xylazine

Xylometazoline

Yttrium-90 chloride

Zafirlukast

Zalcitabine

Zanamivir

Zidovudine

Zipeprol

Ziprasidone

Zofenopril

Zolendronic acid

Zolmitriptan

Zolpidem

Zopiclone

Zoxazolamine

Zuclopenthixol

[S 219/2017 wef 01/05/2017]

PART 2

CLASSES OF THERAPEUTIC PRODUCTS

1. Anti-toxins
2. Anti-venoms
3. Insulins
4. Plasma derivatives
5. Androgen, oestrogen or progestogen hormones
6. Vaccines

SECOND SCHEDULE — *continued*

PART 3

ACTIVE INGREDIENTS IN PHARMACY-ONLY MEDICINES

Albendazole

Alverine

Amorolfine

Amyl nitrite

Bambuterol

Benzydamine

Brompheniramine

Buclizine

Butyl aminobenzoate

Carbinoxamine

Carbocysteine

Cetirizine

Cinnarizine

Dexchlorpheniramine

Dicycloverine

Diphenhydramine

Diphenoxylate

Flunarizine

Levodropropizine

Loperamide

Loratadine

Mebendazole

Mebeverine

Naphazoline

Nicotine

Oxethazaine

Parachlorophenol

SECOND SCHEDULE — *continued*

Phenyltoloxamine

Pholcodine

Podophyllum resin

Podophyllotoxin

Policresulen

Procaterol

Pseudoephedrine

Sodium cromoglycate

Tetrahydrozoline

Tolnaftate

Triprolidine

Tyrothricin

THIRD SCHEDULE

Regulations 11(*d*) and 12(*b*)

First column	*Second column*	*Third column*
Class of persons	*Type of prescription-only medicine*	*Conditions*
1. The owner or the master of a ship which does not carry a doctor on board as part of her crew	All prescription-only medicines	The supply must be necessary for the treatment of persons on the ship
2. Persons requiring prescription-only medicines for the purpose of enabling them, in the course of any business carried on by them, to comply with any requirements made by or under any written law with	Such prescription-only medicines as specified in the relevant written law	The supply — (*a*) must be for the purpose of enabling the persons to comply with any requirements made by or under any written law; and (*b*) is subject to such conditions and is to

THIRD SCHEDULE — *continued*

First column	*Second column*	*Third column*
Class of persons	*Type of prescription-only medicine*	*Conditions*
respect to the medical treatment of their employees		be made in such circumstances as specified in the relevant written law
3. An Independent Duty Corpsman (IDC) deployed on Republic of Singapore Navy (RSN) vessels who has been authorised by the Chief Navy Medical Officer to administer prescription-only medicines	All prescription-only medicines listed in the IDC Medications List approved by the Chief Navy Medical Officer	An IDC — (*a*) must not administer the prescription-only medicines to any person other than personnel on board RSN vessels when the vessels are out at sea, or on military operations and exercises; (*b*) must carry out the administration of the prescription-only medicines in accordance with IDC clinical protocols approved by the Chief Navy Medical Officer; and (*c*) must keep proper records of the IDC's administration of the prescription-only medicines

FOURTH SCHEDULE

Regulation 20(2)

First column	*Second column*
Substance	*Term to be used*
1. Tartrazine	tartrazine (Code E102)
	tartrazine (Code 102)
	tartrazine (Code FD and C Yellow No. 5)
2. Benzoic acid	benzoic acid
	benzoic acid (Code E210)
3. Sodium benzoate	sodium benzoate
	sodium benzoate (Code E211)

FIFTH SCHEDULE

Regulation 20(3)

CAUTIONARY INFORMATION TO BE LABELLED ON THERAPEUTIC PRODUCTS

First column	*Second column*
Therapeutic product	*Cautionary information*
1. Therapeutic product containing aspirin or acetylsalicylic acid for oral administration	Caution: Not to be given to persons below 16 years of age except under the direction of a doctor.
2. Therapeutic product containing any of the following substances for oral administration: (*a*) Diphenoxylate (*b*) Loperamide (*c*) The following anti-histamine substances: Antazoline Azatadine Bamipine	Caution: This may cause drowsiness. If affected, do not drive or operate machinery.

FIFTH SCHEDULE — *continued*

First column	*Second column*
Therapeutic product	*Cautionary information*
Bromodiphenhydramine	
Bromopheniramine	
Buclizine	
Carbinoxamine	
Chlorcyclizine	
Chlorpheniramine	
Cinnarizine	
Clemastine	
Clemizole	
Cyclizine	
Cyproheptadine	
Dexchlorpheniramine	
Dimethpyrindene	
Diphenhydramine	
Diphenylpyraline	
Doxylamine	
Embramine	
Flunarizine	
Homochlorcyclizine	
Isothipendyl	
Levocabastine	
Mebhydrolin	
Meclastine	
Meclozine	
Mepyramine	
Mequitazine	
Methdilazine	

FIFTH SCHEDULE — *continued*

First column	*Second column*
Therapeutic product	*Cautionary information*
Oxatomide	
Oxomemazine	
Phenindamine	
Pheniramine	
Phenyltoloxamine	
Promethazine	
Pyrathiazine	
Pyrrobutamine	
Thenalidine	
Thenyldiamine	
Thiazinamium	
Tolpropamine	
Tripelennamine	
Triprolidine	

SIXTH SCHEDULE

Regulations 41(2), 42(2), 61(2), 62(3) and (4), 63(3) and (4), 64 and 68

FEES

1. Application fee for, or for renewal of, a manufacturer's licence for —		
	(*a*) manufacture of external preparations only	$1,500
	(*b*) manufacture of oral preparations only	$1,500
	(*c*) manufacture of external and oral preparations only	$2,000
	(*d*) manufacture of sterile preparations, or other types of dosage forms or dosage form combinations not described in paragraphs (*a*), (*b*) and (*c*)	$3,000
	(*e*) primary (with or without secondary) packaging	$1,000

SIXTH SCHEDULE — *continued*

(*f*) secondary packaging only	$600
2. Application fee for amending a manufacturer's licence —	
(*a*) without site inspection (administrative amendment)	$50
(*b*) without site inspection (for a manufacturer carrying out packaging only)	$50
(*c*) with site inspection (for a manufacturer carrying out packaging only)	$500
(*d*) with site inspection (for all other manufacturers)	$1,000
3. Application fee for, or for renewal of, an importer's licence for —	
(*a*) any therapeutic product	$500
(*b*) any therapeutic product imported under one of the following regulations:	$200
(i) regulation 5(1)(*b*)(ii) (for scientific education, etc.)	
(ii) regulation 5(1)(*b*)(iii) (for export only)	
(iii) regulation 5(1)(*b*)(iv) or (v) (for supply to a ship or an aircraft)	
4. Application fee for an importer's licence for a consignment of any therapeutic product imported under regulation 5(1)(*b*)(ii), (iii), (iv) or (v)	$100 per consignment
5. Application fee for amending an importer's licence —	
(*a*) without site inspection (administrative amendment)	$50
(*b*) with site inspection	$300
6. Application fee for approval to import or export therapeutic products containing psychotropic substances	$100 per consignment
7. Application fee for approval to import registered therapeutic products under regulation 5(1)(*b*)(vii)	$250 per consignment
8. Application fee for, or for renewal of, a wholesaler's licence for any therapeutic product	$500
9. Application fee for amending a wholesaler's licence —	
(*a*) without site inspection (administrative amendment)	$50

SIXTH SCHEDULE — *continued*

(*b*) with site inspection	$300
10. Application fee for, or for renewal of, an importer's licence and a wholesaler's licence for any therapeutic product	$900
11. Registering one or more innovator products which have not yet been approved by any competent drug regulatory agency and for which the Authority will conduct a full evaluation:	
(*a*) application fee for the initial screening	$2,750
(*b*) evaluation fee	$82,500
12. Registering an innovator product which is approved by at least one competent drug regulatory agency and for which the Authority will conduct an abridged evaluation:	
(*a*) application fee for the initial screening (for each product)	$550
(*b*) evaluation fee for a single-strength product or the first product in a series of products of different strengths	$11,000
(*c*) evaluation fee for each subsequent product in a series of products of different strengths	$5,500
13. Registering an innovator product which is approved by any reference drug regulatory agency and for which the Authority will conduct a verification evaluation:	
(*a*) application fee for the initial screening (for each product)	$550
(*b*) evaluation fee for a single-strength product or the first product in a series of products of different strengths	$16,500
(*c*) evaluation fee for each subsequent product in a series of products of different strengths	$5,500
14. Registering a generic drug product which is approved by at least one competent drug regulatory agency and for which the Authority will conduct an abridged evaluation:	
(*a*) application fee for the initial screening (for each product)	$550

SIXTH SCHEDULE — *continued*

(*b*) evaluation fee for a single-strength product or the first product in a series of products of different strengths	$3,850
(*c*) evaluation fee for each subsequent product in a series of products of different strengths	$2,200
15. Registering a generic drug product which is approved by any reference drug regulatory agency and for which the Authority will conduct a verification evaluation under the Special Scheme for Registration of Generic Medicinal Products from India established pursuant to Chapter 5 of the India-Singapore Comprehensive Economic Cooperation Agreement:	
(*a*) application fee for the initial screening (for each product)	$550
(*b*) evaluation fee for a single-strength product or the first product in a series of products of different strengths	$10,000
(*c*) evaluation fee for each subsequent product in a series of products of different strengths	$5,000
16. Registering a generic drug product which is approved by any reference drug regulatory agency and for which the Authority will conduct a verification evaluation:	
(*a*) application fee for the initial screening (for each product)	$550
(*b*) evaluation fee for a single-strength product or the first product in a series of products of different strengths	$10,000
(*c*) evaluation fee for each subsequent product in a series of products of different strengths	$5,000
17. Fees, in addition to the fees in item 11, 12, 13, 14, 15 or 16, as the case may be, for overseas manufacturers:	
(*a*) application fee for verification of Good Manufacturing Practice Standard	$600
(*b*) evaluation fee for Quality System Dossier	$4,500
(*c*) evaluation fee for on-site audit —	

SIXTH SCHEDULE — *continued*

(i) in an ASEAN country	$18,000
(ii) in a non-ASEAN country in Asia	$20,000
(iii) outside Asia	$24,000
18. Registration fee for a therapeutic product	Nil
19. Annual retention fee under regulation 68(4)	$300
20. For the Authority's approval —	
(*a*) to make a major variation to a registered therapeutic product, for which the Authority will conduct a full evaluation —	
(i) application fee for the initial screening for a series of products of the same proprietary name	$2,500
(ii) evaluation fee for a series of products of the same proprietary name	$51,000
(*b*) to make a major variation to a registered therapeutic product, for which the Authority will conduct an abridged evaluation —	
(i) application fee for the initial screening (for each product)	$500
(ii) evaluation fee for a single-strength product or the first product in a series of products of different strengths	$5,500
(iii) evaluation fee for each subsequent product in a series of products of different strengths	$2,750
(*c*) to make a major variation to a registered therapeutic product, for which the Authority will conduct a verification evaluation —	
(i) application fee for the initial screening (for each product)	$500
(ii) evaluation fee for a single-strength product or the first product in a series of products of different strengths	$8,250
(iii) evaluation fee for each subsequent product in a series of products of different strengths	$2,750

SIXTH SCHEDULE — *continued*

21. Application fee for the Authority's approval to make any other variations to a registered therapeutic product where such approval is required (excluding applications to change the forensic classification of the product)	$550
22. Application fee for the following certificates or documents:	
(*a*) a GMP Certificate	$6,000
(*b*) each additional copy of a GMP Certificate	$200
(*c*) a GDP Certificate	$3,500
(*d*) each additional copy of a GDP Certificate	$200
(*e*) certificate of registration or compliance under regulation 61 for a therapeutic product intended for export	$100
(*f*) certificate of approval under regulation 64 for import of a therapeutic product into Singapore	$100

23. In this Schedule —

"competent drug regulatory agency" means a national regulatory authority participating in the World Health Organization's Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, and listed as such on the World Health Organization's website;

"forensic classification" means the classification of a therapeutic product as "prescription-only medicine", "pharmacy-only medicine" or "general sale list medicine";

"generic drug product" means a therapeutic product containing a chemical entity or a combination of chemical entities that is essentially similar to a registered therapeutic product;

"innovator product" means a therapeutic product containing any new chemical or biological entity, new combination of chemical or biological entities, new dosage form or new route of administration;

"major variation", in relation to a therapeutic product, means any change relating to the intended purpose or recommended dosage of, patient groups for, or clinical trial information on, the therapeutic product;

"primary packaging", in relation to a therapeutic product, means the enclosure of the product in a container which is labelled before the product is sold or supplied;

SIXTH SCHEDULE — *continued*

"reference drug regulatory agency" means a national regulatory authority specified by the Authority on the Authority's website from whose regulatory decisions the Authority takes reference;

"secondary packaging", in relation to a therapeutic product that is already enclosed in the container in which it is to be sold or supplied, means —

(*a*) the labelling of the container, or enclosure of the container with other packaging material (including product informational inserts); or

(*b*) the labelling of the packaging material before the product is sold or supplied in it.

SEVENTH SCHEDULE

Regulation 52(1)(*b*)

First column	*Second column*
Therapeutic product	*Maximum amount allowed*
1. Codeine	(*a*) Oral liquid preparation — not exceeding 15 mg per 5 ml and not exceeding 240 ml in quantity (*b*) Solid preparation — not exceeding 30 mg per dosage unit and not exceeding 20 dosage units in quantity
2. Dextromethorphan	(*a*) Oral liquid preparation — not exceeding 15 mg per 5 ml and not exceeding 240 ml in quantity (*b*) Solid preparation — not exceeding 30 mg per dosage unit and not exceeding 20 dosage units in quantity

Made on 14 July 2016.

KANDIAH SATKUNANANTHAM
Chairman,
Health Sciences Authority,
Singapore.

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