

No. S 000

HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS (THERAPEUTIC PRODUCTS)
REGULATIONS 2015

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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 may be cited as the Health Products (Therapeutic Products) Regulations 2015 and come into operation on 2015.

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, either in its existing state or after it has been dissolved or dispersed in, or diluted or mixed with, some other substance used as a vehicle for the administration;

“administration” means giving or applying to a human being, whether orally, by injection or by introduction into the body in any other way, or by external application, whether by direct contact with the body or not;

“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;

“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;

“in-store pharmaceutical officer” means —

- (a) a qualified pharmacist engaged or employed to provide pharmacy services at or from a licensed retail pharmacy; or
- (b) a person acting under the supervision of the qualified pharmacist when providing pharmacy services at or from the licensed retail pharmacy;

“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;

“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 2015 (G.N. No. S __/2015);

“pharmacy-only medicine” means a registered therapeutic product that is entered into the Register of Health Products under the classification of “pharmacy-only medicine”, and does not include any prescription-only medicine;

“prescription-only medicine” means a registered therapeutic product that is entered into the Register of Health Products under the classification of “prescription-only medicine”, and does not include any pharmacy-only medicine;

“private hospital” means a private hospital that is licensed under the Private Hospitals and Medical Clinics Act (Cap. 248);

“proprietary designation” 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 Pharmacies 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;

“specified publication” means any of the following:

- (a) the European Pharmacopoeia;
- (b) the British Pharmacopoeia;
- (c) the US 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 whatever 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) of, dosage strength of, or indications of intended use for, the therapeutic product;
- (e) any physical characteristics or presentation of the therapeutic product not referred to in paragraphs (a) to (d);

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- (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 it;
 - (iii) the name, contact details and identity card or other identification document number of the patient;
 - (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 2015 (G.N. No. S xx/2015).

PART 2**MANUFACTURE AND IMPORT OF THERAPEUTIC PRODUCTS***Division 1 — Manufacture***Requirements for 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 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 the therapeutic product 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 so far as it relates to the therapeutic product.

Division 2 — Import

Requirements for issue of importer's licence

5. 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 the therapeutic product 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 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 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

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- other written law, for the treatment of persons on board that ship;
- (v) is intended to be supplied for 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) if the applicant is not the registrant of the therapeutic product, is nevertheless in all respects the same as the therapeutic product registered by the registrant under the Act; and
- (c) the applicant is able to comply with the requirements in the Guidance Notes on Good Distribution Practice for importers set out on the Authority's website if the therapeutic product is imported in accordance with paragraph (b)(i), (vi) and (vii).

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 every 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

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 every 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 every 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 specified (but not excepted) in Part 1 of the Second Schedule;
 - (b) is within any class of therapeutic product specified in Part 2 of the Second Schedule; or
 - (c) is a preparation containing an active ingredient specified in Part 3 of the Second 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.**—(1) A person must not supply by retail sale any prescription-only medicine unless —
- (a) the person is an in-store pharmaceutical officer providing pharmacy services at or from a licensed retail pharmacy and

the prescription-only medicine is supplied in accordance with the controlled conditions in paragraph (2);

- (b) the supply is made by a person authorised to do so in a licensed healthcare institution to a patient of that healthcare institution, 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 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 listed in the first column of the Third Schedule, the prescription-only medicine is of the type listed 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.

(2) The controlled conditions for an in-store pharmaceutical officer to supply by retail sale a prescription-only medicine are —

- (a) the prescription-only medicine is supplied —
 - (i) to a patient in accordance with a valid prescription given by a qualified practitioner; or
 - (ii) in accordance with the oral or written instructions of a qualified practitioner who undertakes, when giving the instructions, to give a valid prescription within 24 hours after giving the instructions; or
- (b) the prescription-only medicine supplied —
 - (i) is specified in the list of prescription-only medicines exempted for limited sale and supply;
 - (ii) is labelled to show a maximum daily dose not exceeding that specified in the list of prescription-only medicines exempted for limited sale and supply;

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- (iii) does not exceed the maximum supply specified in the list of prescription-only medicines exempted for limited sale and supply;
 - (iv) is to a person who is of or above any minimum age specified in the list of prescription-only medicines exempted for limited sale and supply; and
 - (v) is recorded by the in-store pharmaceutical officer in the manner prescribed in regulation 16(2).

(3) In this regulation, “list of prescription-only medicines exempted for limited sale and supply” means the list, as published on the Authority’s website, of therapeutic products classified as prescription-only medicines that may be supplied by an in-store pharmaceutical officer at or from a licensed retail pharmacy without the need for a valid prescription.

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 instructions of a qualified practitioner; or
- (b) the person is listed in the first column of the Third Schedule, the prescription-only medicine is listed 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 of pharmacy-only medicine

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

- (a) the supply is made at or from a licensed retail pharmacy and by an in-store pharmaceutical officer engaged or employed by the holder of the pharmacy licence for the licensed retail pharmacy;

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- (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 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, in respect of the supply, keep a record of all such supplies at the premises where the supply is made, and the record must contain all the following particulars:
- (a) the date of the supply;
 - (b) the name, identity card or other identification 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 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 from 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 240ml of any one or more codeine cough preparations to any one customer on any one occasion;
- (b) must not supply any codeine cough preparation to the same customer more than once within a period of 4 days (including Sundays and public holidays); and
- (c) must provide professional counselling on the use of codeine cough preparations to each customer to whom the qualified pharmacist supplies any codeine cough preparation on each occasion of supply to that customer.

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

- (a) the automatic vending machine is sufficiently equipped and secure to ensure appropriate storage conditions for the medicine;
- (b) the medicine is labelled and packaged in accordance with the conditions attached by the Authority to the registration of the medicine;
- (c) the person’s name and contact information is prominently displayed on the automatic vending machine.

(2) In paragraph (1), “general sale list medicine” means a registered therapeutic product entered into the Register of Health Products under the classification of “general sale list medicine”.

Division 3 — 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 a record, complying with paragraphs (2) and (3), of all such supplies at the premises where the therapeutic product is supplied.

(2) The record in paragraph (1) must contain all the following particulars:

- (a) the date of supply;
- (b) the name, contact details and identity card or other identification document number of the person to whom the therapeutic product is supplied;
- (c) the name of the therapeutic product 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, the name and the 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 —

- (a) by wholesale; or
- (b) by an in-store pharmaceutical officer in accordance with the controlled conditions in regulation 11(2)(a)(ii).

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 appropriate non-proprietary name or the proprietary designation;
- (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 —

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- (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 such staff, premises, equipment and facilities as are necessary to prevent the deterioration of the therapeutic product during handling, storage and distribution; 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 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

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- (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 supplied 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 appropriate non-proprietary name and the proprietary designation;
- (b) where the appropriate non-proprietary name is included on the label of the therapeutic product, the appropriate quantitative particulars of any active ingredient of the therapeutic product;
- (c) where the therapeutic product is a prescription-only medicine or pharmacy-only medicine, the name and address of its supplier;
- (d) an appropriate control number, such as a serial number, batch number or lot number;
- (e) the expiry date of the therapeutic product;
- (f) where the therapeutic product is registered, the registration number assigned to the registered therapeutic product by the Authority.

(2) All information accompanying the therapeutic product referred to in paragraph (1), including the statement referred to in paragraph (3) and the caution referred to in paragraph (4) —

(a) must be provided in English, and may, in addition, be provided in any other language; and

(b) must be legible and permanent.

(3) Where a therapeutic product contains any substance specified in the first column of the Fourth Schedule, the 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.

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

(5) Where a container, which is in the form of a bubble, blister or other sealed unit, is part of a continuous series comprising a sheet or strip of like containers, paragraph (4) is taken to have been complied with if the caution referred to in that paragraph is printed or displayed or otherwise marked in a prominent position at frequent intervals on the sheet or strip of the container.

Corrective measures in relation to contravening trade descriptions

21.—(1) Where any manufacturer, importer, supplier or registrant of a therapeutic product has applied a trade description in contravention of regulation 19 or 20, the Authority may order that manufacturer, importer, supplier or registrant, as the case may be, to do any or all 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;

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- (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) A person to whom an order under paragraph (1) 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.
- (3) If a person to whom an order under paragraph (1) is directed fails to comply with the order in accordance with paragraph (2), the person 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.
- (4) Without prejudice to paragraph (3), the Authority may take such steps as it thinks reasonable and necessary to implement the requirements of an order directed to any person under paragraph (1), and recover any costs and expenses reasonably incurred by it 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 use 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 take into consideration 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 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, an applicant for the registration of a therapeutic product 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 set out in Part 1 of the Sixth Schedule, 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 for the registration of a therapeutic product 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 referred to in paragraph (2) —

- (a) the name and address of the proprietor of the patent;
- (b) whether —

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- (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) The Authority need not determine the application until the applicant has complied with paragraph (2) and, where applicable, paragraphs (3) and (6), to the reasonable satisfaction of the Authority.
- (5) The Authority must require the applicant for the registration of a therapeutic product to comply with the requirements in paragraph (6) 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 so comply.
- (6) For the purposes of paragraph (5), the Authority must require the applicant for the registration of a therapeutic product to —
- (a) serve, in accordance with section 67 of the Act, on the proprietor of the patent under the Patents Act that is in force in respect of the therapeutic product, a notice in the form set out in Part 2 of the Sixth Schedule; and
 - (b) furnish to the Authority such evidence of the service of the notice as the Authority may require.
- (7) If the Authority is satisfied that a notice referred to in paragraph (6)(a) 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 a court or the Registrar of Patents or a Deputy Registrar of Patents holding office under the Patents Act, for an order or a declaration as specified in that notice; and
- (b) give written notice to the Authority stating that such application has been made, accompanied by evidence of the application.

(8) The Authority may register the therapeutic product without further notice to the proprietor, if —

- (a) an application for the order or declaration referred to in paragraph (7)(a) has been made; and
- (b) at the expiry of 30 months after the date of the application for the order or declaration, the order or declaration has not been obtained.

(9) If, before the expiry of the period referred to in paragraph (8)(b), the proprietor notifies the Authority that the order or declaration referred to in paragraph (7)(a) has been obtained and submits a copy of such order or declaration, the Authority may in its discretion require the applicant to withdraw the applicant's application.

(10) For the purpose 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).

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 referred to 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 and confidential supporting information, the Authority, during the protected period in relation to such confidential supporting information —

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

(b) must not use that confidential supporting information for any purpose other than to determine whether to grant that application.

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

“application” means an application to register a therapeutic product;

“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 from 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 purposes of determining whether to grant any application other than the application to which it relates —
 - (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 purposes 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 referred to 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.

Publication 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 publish, 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 published under this paragraph exclude —

- (a) any trade secret; and
- (b) any information that has commercial value that would be, or would be likely to be, diminished by 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 (referred to in this regulation as 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 being used for the manufacture, supply or storage of therapeutic products; and
- (b) any conveyances that are 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 conveyances referred to in paragraph (1); or
 - (ii) any property or material found on the premises or in the conveyances.

(3) A person who refuses or fails, without reasonable excuse, to comply with any requirement of an enforcement officer under paragraph (2)(a) 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.

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 referred to 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 —

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- (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(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 referred to 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 description 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 to whom the therapeutic product is supplied by *P*;
 - (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 description of the therapeutic product;
 - (ii) the date on which the therapeutic product was supplied;

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- (iii) the name and address of the person to whom the therapeutic product was 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 referred to in paragraph (1) must ensure that every record referred to in paragraph (1) —

- (a) contains all of the following information:

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- (i) the proprietary name or description 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 prolong 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 referred to 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 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.

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 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 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;

- (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 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; and
- (c) must not use, for any purpose specified 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 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; and
- (d) must not use, for any purpose specified 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; and

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

(e) 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 electronic mail 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; and
- (d) 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 (but is not limited to) 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 referred to 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; and
- (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 Seventh 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. 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 the quality, safety or efficacy of any therapeutic product to which the registrant's registration relates, inform the Authority of such information.

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 a benefit-risk evaluation 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 of 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 where standards established for the operation of clean rooms and the preparation of sterile products are in place and properly documented;
 - (ii) in accordance with the written instructions of a qualified practitioner practising at any private hospital or medical clinic, for the use of a patient under the care of the qualified practitioner;
 - (iii) 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) It does not matter whether the patient referred to in paragraph (1)(c)(ii) is or is not a patient at the private hospital or medical clinic.

(3) 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.

(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 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).

(6) A person who fails to comply with paragraph (5) 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.

(7) The Authority may require a healthcare institution licensee who compounds a therapeutic product under paragraph (1) to furnish records of any stability study referred to 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(3) 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(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, 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) If the therapeutic product is to be compounded for the purpose of supplying to the owner or the master of a ship, the therapeutic product must be —

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

(4) 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.

(5) 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).

(6) A person who fails to comply with paragraph (5) 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.

(7) 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 referred to 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 a ship or an aircraft in accordance with the requirements in regulation 5(b)(iv) or (v) respectively;
- (c) is for the purpose of scientific education or research and development;
- (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 Eighth 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 person —

- (a) as recommended by —
 - (i) the manufacturer of the therapeutic product; or
 - (ii) a foreign doctor or dentist by way of a written recommendation, or a qualified practitioner by way of a valid prescription,

if the therapeutic product does not contain any active ingredient specified in the first column of Part 1 of the Second Schedule; or

- (b) as recommended by a foreign doctor or dentist by way of a written recommendation, or a qualified practitioner by way of a valid prescription, if the therapeutic product —
 - (i) contains an active ingredient specified in the first column of Part 1 of the Second Schedule; and
 - (ii) does not fall within the exceptions specified in the second column of Part 1 of that Schedule.

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 such staff, premises, equipment and facilities for the distribution of the therapeutic product as are necessary to prevent the deterioration of the therapeutic product.

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(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(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 referred to 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 referred to 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.

(4) In this regulation, "non-clinical purpose" means any purpose not involving any application of a therapeutic product on, or use of a therapeutic product by, humans.

PART 8

EXCEPTIONS — SUPPLY OF THERAPEUTIC PRODUCTS WITHOUT REGISTRATION

Prescribed exceptions

58. For the purposes of section 15(1) of the Act, 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;

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- (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;
 - (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(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 qualified pharmacist 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;

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- (j) the supply of a therapeutic product for a ship or an aircraft in accordance with the requirements in regulation 5(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 is —
 - (i) manufactured solely for export; or
 - (ii) imported solely for re-export.

Supply of therapeutic products compounded under contractual agreement with licensed manufacturer

59.—(1) Without prejudice to any other provision in this Part, 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, unless the health product is registered, if —

- (a) the cancellation of the registration is either —
 - (i) made by the Authority under section 37(2) of the Act because of the registrant's failure to pay the prescribed retention fee within the prescribed time; or
 - (ii) due to an application by the registrant to cancel the registration 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 Seventh 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 upon assessment of satisfactory conformity with a Good Manufacturing Practice Standard, issue a GMP Certificate to the manufacturer subject to such 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 from the date of assessment of satisfactory conformity with a Good Manufacturing Practice Standard.

(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 Seventh Schedule.

(4) In this regulation and the Seventh Schedule —

“Good Manufacturing Practice Standard” means the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme Guide to Good Manufacturing Practice for Medicinal Products or such other good manufacturing practice standard approved by the Authority; and

“GMP Certificate” means a certificate issued by the Authority to certify compliance with the Good Manufacturing Practice Standard.

Certificate of distribution standard of therapeutic products

63.—(1) The Authority may, on the application of a person who distributes a therapeutic product and upon assessment of satisfactory conformity with a Good Distribution Practice Standard, issue a GDP Certificate to the applicant subject to such 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 from the date of assessment of satisfactory conformity with a Good Distribution Practice Standard.

(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 Seventh Schedule.

(4) For the purposes of this regulation and the Seventh Schedule —

“Good Distribution Practice Standard” means the Authority’s Guidance Notes on Good Distribution Practice or any such other good distribution practice standard approved by the Authority; and

“GDP Certificate” means a certificate issued by the Authority to certify compliance with the Good Distribution Practice Standard.

Other certificates or documents

64. The Authority may, on the application of any person and upon payment of the relevant fee specified in the Seventh 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 Seventh Schedule are payable in respect of the matters set out in that Schedule.

(2) A fee for an application referred to in the Seventh Schedule must be paid when the application is submitted to the Authority.

(3) For the purposes of section 31(a) of the Act, the retention fee for the retention of the registration of a therapeutic product is payable on or before each anniversary of the date of registration of the therapeutic product.

(4) 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

PSYCHOTROPIC SUBSTANCES

1. The following substances:

Allobarbitol
Alprazolam
Amfepramone
Aminorex
Amobarbital
Barbital
Bromazepam
Brotizolam
Butalbitol
Butobarbital
Camazepam
Cathine
Chlordiazepoxide
Clobazam
Clonazepam
Clorazepate
Clotiazepam
Cloxazolam
Cyclobarbitol
Delorazepam
Diazepam
Estazolam
Ethchlorvynol
Ethinamate
Ethylloflazepate
Etilamfetamine

Fencamfamin
Fenproporex
Fludiazepam
Flurazepam
Glutethimide
Halazepam
Haloxazolam
Ketazolam
Lefetamine
Loprazolam
Lorazepam
Lormetazepam
Mazindol
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 and 52(2)

PART 1

ACTIVE INGREDIENTS IN PRESCRIPTION-ONLY MEDICINES

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
(±)-4-ethyl-2, 5-dimethoxy- α -phenethylamine (2C-E)	
(±)-N-ethyl--methyl-3,4-(methylenedioxy)phenethylamine	
2, 5-Dimethoxy-4-ethylamphetamine (DOET)	
2, 5-Dimethoxyamphetamine (DMA)	
2-Deoxy-2-[18F] fluoro-d-glucose	
2-Phenylcinchoninic acid; 2-salicylcinchoninic acid	
3, 4, 5-Trimethoxyamphetamine (TMA)	
3, 4-Methylenedioxymethamphetamine (MDMA)	
3-Di-n-butylaminomethyl-4,5,6-trihydroxyphthalide	Preparations intended for external application only;

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
4-Cyano-1-methyl-4-phenylpiperidine	Preparations containing not more than 1% for application in the nose or eye
4-methylaminorex	
4-Phenylpiperidine-4-carboxylic acid	
5-methoxy-3, 4-methylene-dioxyamphetamine (MMDA)	
5-Phenylhydantoin	
Abacavir	
Abatacept	
Abciximab	
Abiraterone	
Acamprosate	
Acarbose	
Acebutolol	
Aceclofenac	
Acemetacin	
Acepromazine	
Acetanilide; alkyl acetanilides	
Acetazolamide	
Acetohexamide	
Acetorphine	
Acetylcarbromal	
Acetyldigoxin	
Acetyldihydrocodeine	
Acetylmethadol	
Acetylstrophanthidin	
Acipimox	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Acitretin	
Acrivastine	
Actinomycins	
Acyclovir	Preparations for external application only, not exceeding 5% for treatment of cold sore Maximum supply: 2g
Adalimumab	
Adapalene	
Adefovir	
Adicillin	
Adiphenine	
Adrenaline	
Adreno-corticotrophic hormone (ACTH)	
Afatinib	
Aflibercept	
Agalsidase beta	
Agomelatine	
Alatrofloxacin	
Alcaftadine	
Alclofenac	
Alclometasone	
Alcuronium	
Aldesleukin	
Aldosterone	
Alefacept	
Alemtuzumab	
Alendronic acid	
Alfacalcidol	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Alfentanil	
Alfuzosin	
Algestone	
Alglucosidase alfa	
Aliskiren	
Allobarbitone	
Allopurinol	
Allylisopropylacetylurea	
Allyloestrenol	
Allyprodine	
Alminoprofen	
Almitrine	
Alosetron	
Alphacalcidol	
Alphacetylmethadol	
Alphachloralose	
Alphadolone	
Alphameprodine	
Alphamethadol	
Alphaprodine	
Alphaxalone	
Alprazolam	
Alprenolol	
Alprostadiol	
Alseroxylon	
Alteplase	
Altretamine	
Amantadine	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Amibenonium	
Ambuside	
Ambutonium	
Ametazole	
Amethocaine	
Amfepramone	
Amidopyrine	
Amifostine	
Amikacin	
Amiloride	
Amineptine	
Aminocaproic acid	
Aminogluthethimide	
Aminophylline	
Aminopterin	
Aminorex	
Amiodarone	
Amisulpride	
Amitriptyline	
Amlodipine	
Ammonium lactate	
Amoxicillin	
Amphetamine	
Amphomycin	
Amphotericin B	
Ampicillin	
Amprenavir	
Amrinone	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Amsacrine (M-AMSA)	
Amylobarbitone	
Amylocaine	
Anagrelide	
Anastrozole	
Ancrod	
Androsterone	
Angiotensin amide	
Anidulafungin	
Anileridine	
Anistreplase	
Antazoline	Preparations intended for external application only; Preparations containing not more than 1% for application in the nose or eye
Apixaban	
Apomorphine	
Apraclonidine	
Apramycin	
Aprepitant	
Aprobarbitone	
Aprotinin	
Aripiprazole	
Arotinolol	
Arsphenamine	
Arteether	
Artemether	
Artemisinin	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Artesunate	
Articaine	
Asenapine	
Aspoxicillin	
Astemizole	
Atazanavir	
Atenolol	
Atomoxetine	
Atorvastatin	
Atosiban	
Atovaquone	
Atracurium	
Atropine	
Auranofin	
Axitinib	
Azacididine	
Azacyclonol	
Azaperone	
Azapropazone	
Azasetron	
Azatadine	Preparations intended for external application only; Preparations containing not more than 1% for application in the nose or eye
Azathioprine	
Azelaic	Preparations for external application only, containing less than or equal to 20% when supplied according to the following conditions: Indications: Mild to Moderate

<i>First column</i> Active ingredient	<i>Second column</i> Exceptions
Azelastine	Acne Vulgaris Maximum daily dose: Apply to the affected area twice daily Maximum supply: 30g Minimum age: 12 years
Azidamphenicol	
Azidocillin	
Azilsartan	
Azithromycin	
Aztreonam	
Bacampicillin	
Bacitracin	
Baclofen	
Bambermycin	
Bamipine	Preparations intended for external application only; Preparations containing not more than 1% for application in the nose or eye
Barbitone	
Barbituric acid	
Basiliximab	
Becaplermin	
Beclamide	
Beclomethasone	Preparations intended for nasal application only, when supplied according to the following conditions: Indications: Prevention and treatment of allergic rhinitis. Maximum daily dose: 200 mcg/nostril

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
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	
Benzilium	
Benzocaine	Preparations intended for external application only, containing not more than 1%
Benzocetamine	
Benzoestrol	Preparations intended for external application only, containing not more than 0.04%

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Benzoylmorphine	
Benzphetamine	
Benzquinamide	
Benzthiazide	
Benztropine and its homologues	
Benzyl fentanyl	
Benzylmorphine	
Benzylpenicillin	
Besifloxacin	
Betahistine	
Betameprodine	
Betamethadol	
Betamethasone	
Betaprodine	
Betaxolol	
Bethanechol	
Bethanidine	
Betiatide	
Bevacizumab	
Bevonium methyl sulphate	
Bezafibrate	
Bezitramide	
Bicalutamide	
Bicisate dihydrochloride	
Bifonazole	Preparations intended for external application; Preparations for vaginal application
Bimatoprost	
Biperiden	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Bisoprolol	
Bleomycin	
Boceprevir	
Boldenone undecenoate	
Bonsentan	
Bopindolol	
Bortezomib	
Bosentan	
Botulinum toxin	
Brentuximab	
Bretylium	
Brimonidine	
Brinzolamide	
Brolamfetamine	
Bromazepam	
Bromocriptine	
Bromodiphenhydramine	Preparations intended for external application only; Preparations containing not more than 1% for application in the nose or eye
Bromvaletone	
Brotizolam	
Budesonide	Preparations for nasal application only, when supplied according to the following conditions: Indications: Prevention and treatment of allergic rhinitis Maximum daily dose: 200 mcg/nostril Maximum supply: up to 3 months' duration

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions Minimum age: 18 years
Bufexamac	
Buflomedil	
Buformin	
Bumadizone calcium	
Bumetanide	
Bunazosin	
Buphenine hydrochloride	
Bupivacaine	
Bupranolol	
Buprenorphine	
Bupropion	
Buserelin	
Buspirone	
Busulphan	
Butacaine	
Butalbital	
Butamirate	
Butanilcaine	
Butizide	
Butobarbitone	
Butoconazole	
Butriptyline	
Butropium bromide	
Butylchloral hydrate	
Cabazitaxel	
Cabergoline	
Cabimicina	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Calcipotriol	
Calcitonin	
Calcitriol	
Calcium barbiturate	
Calcium carbimide	
Calcium dobesilate	
Calfactant	
Camazepam	
Canagliflozin	
Canakinumab	
Candesartan	
Candicidin	
Capecitabine	
Capreomycin	
Captodiame	
Captopril	
Caramiphen	
Carbachol	
Carbamazepine	
Carbenicillin	
Carbenoxolone	Preparations intended for external application only
Carbetocin	
Carbidopa	
Carbimazole	
Carboplatin	
Carboprost	
Carbromal	
Carbutamide	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Carfecillin	
Carfentanil	
Carisoprodol	
Carmustine	
Carperidine	
Carprofen	
Carteolol	
Carvedilol	
Caspofungin	
Cathine	
Cathinone	
Cefaclor	
Cefadroxil	
Cefamandole	
Cefatrizine	
Cefdinir	
Cefepime	
Cefixime	
Cefodizime	
Cefoperazone	
Cefotaxime	
Cefotiam	
Cefoxitin	
Cefpirome	
Cefprozil	
Cefsulodin	
Ceftaroline	
Ceftazidime	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Ceftibuten	
Ceftizoxime	
Ceftriaxone	
Cefuroxime	
Celecoxib	
Cephalexin	
Cephaloglycin	
Cephaloram	
Cephaloridine	
Cephalothin	
Cephaloxin	
Cephazolin	
Cephradine	
Cerivastatin	
Certolizumab	
Cetrorelix	
Cetuximab	
Chenodeoxycholic acid	
Chloral hydrate	
Chlorambucil	
Chloramphenicol	
Chlorcyclizine	Preparations intended for external application only; Preparations containing not more than 1% for application in the nose or eye
Chlordiazepoxide	
Chlormadinone	
Chlormerodrin	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Chlormethiazole	
Chlormezanone	
Chlormidazole	
Chlorothiazide	
Chloroquine	Preparations intended for oral administration when supplied for prophylaxis of malaria
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	
Chromomycin A	
Ciclacillin	
Ciclesonide	
Ciclopirox	
Cilastatin	
Cilazapril	
Cilostazol	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Cimetidine	Preparations intended for oral administration when supplied according to the following conditions: Indications: (a) Short-term relief of heartburn, dyspepsia and hyperacidity; and (b) Prophylactic management of nocturnal heartburn Maximum daily dose: (a) 200 mg; and (b) 100mg (as a single night-time dose) Maximum supply: Up to 2 weeks' duration
Cinacalcet	
Cinchocaine	
Ciprofibrate	
Ciprofloxacin	
Cisapride	
Cisatracurium	
Cisplatin	
Cistracurium	
Citalopram	
Citicoline	
Cladribine	
Clarithromycin	
Clavulanic acid	
Clebopride	
Clemastine	Preparations intended for external

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
	application only; Preparations containing not more than 1% for application in the nose or eye
Clemizole	Preparations intended for external application only; Preparations containing not more than 1% for application in the nose or eye
Clenbuterol	
Clidinium	
Clindamycin	
Clioquinol	
Clobazam	
Clobenzorex	
Clobetasol	
Clobetasone	
Clobutinol	
Clodronic acid	
Clofarabine	
Clofazimine	
Clofedanol	
Clofibrate	
Clomiphene	
Clomipramine	
Clomocycline	
Clonazepam	
Clonidine	
Clonitazene	
Clopamide	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Clopenthixol	
Clopidogrel	
Cloprostenol	
Clorazepate	
Clorexolone	
Clorprenaline	
Clostebol	
Clostridiopeptidase A	
Clotiazepam	
Clotrimazole	Preparations intended for dermatological application containing not more than 1% ; Preparations intended for vaginal application
Cloxacillin	
Cloxacillin benzathine	
Cloxazolam	
Cloxiquine	
Clozapine	
Codeine	
Co-Dergocrine Mesylate	
Colchicine	
Colestipol	
Colimycin	
Colistin	
Corifollitropin alfa	
Corticoirelin	
Cortisone	
Crisantaspase	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Crizotinib	
Cropropamide	
Crotethamide	
Cyclandelate	
Cyclarbamate	
Cyclizine	Preparations intended for external application only; Preparations containing not more than 1% for application in the nose or eye
Cyclobarbitone	
Cyclofenil	
Cyclopenthiazide	
Cyclopentolate	
Cyclophosphamide	
Cycloserine	
Cyclosporin	
Cyclothiazide	
Cycrimine	
Cyproheptadine	Preparations intended for oral administration for treatment of allergic rhinitis
Cyproterone	
Cytarabine	
Dabigatran etexilate mesilate	
Dacarbazine	
Daclizumab	
Dactinomycin	
Dalfopristin	
Dalteparin	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Danazol	
Danthron	
Dantrolene	
Dapagliflozin	
Dapoxetine	
Dapsone	
Daptomycin	
Darbepoetin alfa	
Darunavir	
Dasatinib	
Daunorubicin	
Debrisoquine	
Deferasirox	
Deferiprone	
Deferoxamine	
Degarelix	
Dehydroemetine	
Dehydroepiandrosterone (DHEA)	
Delapril	
Delmadinone	
Delorazepam	
Demecarium	
Demeclocycline	
Demoxycocin	
Denosumab	
Deoxycortone	
Deptropine	
Deserpidine	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Desferrioxamine mesylate	
Desfluorotriamcinolone	
Desflurane	
Desipramine	
Deslanoside	
Desmopressin	
Desogestrel	
Desomorphine	
Desoxymethasone	
Desvenlafaxine	
Dexamethasone	
Dexamphetamine	
Dextimide	
Dexfenfluramine	
Dexketoprofen	
Dexlansoprazole	
Dexmedetomidine	
Dexrazoxane	
Dextromethorphan	
Dextromoramide	
Dextropropoxyphene	
Dextrorphan	
Dextrothyroxine sodium	
Diacetylmorphine	
Diacetylnalorphine	
Diamino-diphenylsulphones	
Diamorphine	
Diampromide	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Diazepam	
Diazoxide	
Dibekacin	
Dibenzepin	
Dibucaine	
Dichloralphenazone	
Dichlorophenarsine	
Dichlorphenamide	
Diclofenac	<p>Preparations intended for external application, containing diclofenac diethylammonium salt equivalent to not more than 1% ;</p> <p>Preparations for oral administration, containing not more than 12.5 mg when supplied according to the following conditions:</p> <p style="padding-left: 40px;">Indication: Short-term treatment (i.e. maximum 3 days) of headache, dental pain, period pain, pain in the joints and ligaments, backache and pain due to injuries, and also to reduce fever in flu-like illnesses</p>
Dicloxacillin	
Didanosine	
Dienoestrol	
Dienogest	
Diethanolamine fusidate	
Diethylcarbamazine	
Diethylthiambutene	
Difenoxin	
Diflucortolone	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Diflunisal	
Digoxin	
Dihydralazine	
Dihydroartemisin	
Dihydrocodeine	
Dihydrocodeinone	
Dihydroergotamine	
Dihydroergotamine	
Dihydroetorphine	
Dihydromorphine	
Dihydrostreptomycin	
Diloxanide	
Diltiazem	
Dimercaprol	
Dimethindene	Preparations intended for external application only; Preparations containing not more than 1% for application in the nose or eye
Dimethisoquin	
Dimethisterone	
Dimethothiazine	
Dimethoxanate	Preparations intended for external application only; Preparations containing not more than 1% for application in the nose or eye
Dimethpyrindene	Preparations intended for external application only; Preparations containing not more than 1% for application in the nose or eye

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Dimethyl 4-sulphamoylphenyl phosphorothioate	
Dimethyl sulphoxide	
Dimethylthiambutene	
Dimethyltubocurarine	
Dinitronaphthols	
Dinitrothymols	
Dinoprost	
Dinoprostone	
Dioxaphetyl butyrate	
Diperodon	Preparations intended for external application only containing not more than 1%
Diphenidol	
Diphenylpyraline	Preparations intended for external application only; Preparations containing not more than 1% for application in the nose or eye
Dipipanone	
Dipivefrin	
Diprophylline	
Dipyridamole	
Dipyron	
Dirithromycin	
Disopyramide	
Distigmine	
Disulfiram	
Disulphamide	
Dithienylallylamines; dithienyl-alkylallylamines	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Dobutamine	
Docetaxel	
Domperidone	<p>Preparations for oral administration containing not more than 10mg or an oral liquid preparation containing not more than 1mg/ml, when supplied according to the following conditions:</p> <p>Indications: Relief of postprandial symptoms of excessive fullness, nausea, epigastric bloating and belching occasionally accompanied by epigastric discomfort and heartburn. Maximum daily dose: 30 mg Maximum supply: 14 days Minimum age: 12 years</p>
Donepezil	
Dopamine	
Doripenem	
Dorzolamide	
Dothiepin	
Doxapram	
Doxazosin	
Doxepin	
Doxofylline	
Doxorubicin	
Doxycycline	
Doxylamine	<p>Preparations intended for external application only; Preparations containing not more than 1% for application in the nose or eye</p>

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Dronedarone	
Droperidol	
Drosperinone	
Drospirenone	
Drostanolone	
Drotebanol	
Drotrecogin alpha	
Duloxetine	
Dutasteride	
Dydrogesterone	
Dyflon	
Ebastine	
Ecainide	
Econazole	Preparations intended for external application; Preparations intended for vaginal application
Ecothiopate iodine	
Ectylurea	
Eculizumab	
Edoxudine	
Edrophonium	
Efalizumab	
Efavirenz	
Eletriptan	
Eltrombopag olamine	
Embramine	Preparations intended for external application only; Preparations containing not more than 1% for application in the nose

<i>First column</i> Active ingredient	<i>Second column</i> Exceptions
Embutramide	or eye
Emedastine	
Emedastine	
Emepromium	
Emtricitabine	
Emylcamate	
Enalapril	
Enalaprilat	
Enflurane	
Enfuvirtide	
Enoxaparin	
Entacapone	
Entecavir	
Eperisone	
Ephedrine; its optical isomers	Preparations for oral administration containing less than 10% of ephedrine or its optical isomers
Epicillin	
Epimestrol	
Epinastine	
Epioestriol	
Epirubicin	
Epthiazide	
Eplerenone	
Epoetin Alfa	
Epoetin Beta	
Epoprostenol	
Eprosartan	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Eptacog alfa	
Eptifibatide	
Erdosteine	
Ergometrine	
Ergotamine	
Ergotoxine	
Eribulin mesylate	
Erlotinib	
Ertapenem	
Erythrityl tetranitrate	
Erythromycin	
Erythropoietin	
Escitalopram	
Esmolol	
Esomeprazole	
Estazolam	
Estramustine	
Etafedrine	
Etanercept	
Ethacrynic acid	
Ethambutol	
Ethamivan	
Ethamsylate	
Ethchlorvynol	
Ethebenecid	
Ethiazide	
Ethinamate	
Ethinylestradiol	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Ethionamide	
Ethisterone	
Ethoglucid	
Ethoheptazine	
Ethopropazine	
Ethosuximide	
Ethotoin	
Ethyl biscoumacetate	
Ethyl loflazepate	
Ethyl p-piperidinoacetylamino benzoate	
Ethylacetanilide	
Ethylmorphine	
Ethylnoradrenaline	
Ethylloestrenol	
Ethylstibamine	
Ethynodiol	
Etidronic acid	
Etilamfetamine	
Etodolac	
Etofenamate	
Etofibrate	
Etofylline clofibrate	
Etomidate	
Etonitazene	
Etonogestrel	
Etoposide	
Etoricoxib	
Etorphine	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Etoxidine	
Etravirine	
Etretinate	
Etryptamine	
Everolimus	
Exametazime	
Exemestane	
Exenatide	
Ezetimibe	
Famciclovir	
Famotidine	Preparations intended for oral administration, when supplied according to the following conditions: Indications: Short-term relief of heartburn, dyspepsia and hyperacidity. Maximum daily dose: 20 mg Maximum supply: Up to 2 weeks' duration
Famprofazone	
Fazadinium	
Felbinac	
Felodipine	
Felypressin	
Fencamfamin	
Fenclofenac	
Fenetylline	
Fenfluramine	
Fenofibrate	
Fenoprofen	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Fenoterol	
Fenoverine	
Fenpipramide	
Fenpiprane	
Fenproporex	
Fentanyl	
Fenticonazole	
Feprazone	
Ferric carboxymaltose	
Ferucarbotran	
Filgrastim	
Finasteride	
Fingolimod	
Flavomycin	
Flavoxate	
Flecainide	
Floxuridine	
Fluanisone	
Fluclorolone	
Flucloxacillin	
Fluconazole	Preparations intended for external application; Preparations intended for vaginal application
Flucytosine	
Fludarabine phosphate	
Fludiazepam	
Fludrocortisone	
Flufenamic acid	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Flugestone	
Flumazenil	
Flumedroxone	
Flumethasone	
Flumethiazide	
Flunisolide	
Flunitrazepam	
Fluocinolone	
Fluocinonide	
Fluocortolone	
Fluopromazine	
Fluoro-2-deoxy-d-glucose	
Fluoroacetamide	
Fluoroacetanilide	
Fluorometholone	
Fluorouracil	
Fluothane	
Fluoxetine	
Fluoxymesterone	
Flupenthixol	
Fluperolone	
Fluphenazine	
Fluprednidene	
Fluprednisolone	
Fluprostenol	
Flurandrenolone	
Flurazepam	
Flurbiprofen	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Flurethidine	
Fluspirilene	
Flutamide	
Fluticasone	Preparations intended for nasal application for allergic rhinitis
Fluvastatin	
Fluvoxamine	
Follicle stimulating hormone (FSH)	
Follitropin alfa	
Fondaparinux	
Formestane	
Formosulphathiazole	
Formoterol	
Fosamprenavir	
Fosaprepitant dimeglumine	
Foscarnet	
Fosfestrol	
Fosfomicin	
Fosinopril	
Fotemustine	
Framycetin	
Frusemide	
Ftorafur	
Fulvestrant	
Fumagillin	
Furaltadone	
Furazolidone	
Fusafungine	
Fusidic acid	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Gabapentin	
Gadobenate dimeglumine	
Gadobutrol	
Gadodiamide	
Gadopentetic acid	
Gadoteric acid	
Gadoversetamide	
Gadoxetate	
Gadoxetic acid	
Galantamine	
Gallamine	
Gallium	
Ganciclovir	
Ganirelix	
Gatifloxacin	
Gefitinib	
Gemcitabine	
Gemeprost	
Gemfibrozil	
Gemtuzumab ozogamicin	
Gentamicin	
Gestodene	
Gestrinone	
Gestronol	
Gimeracil	
Glafenine	
Glibenclamide	
Glibornuride	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Gliclazide	
Glimepiride	
Glipizide	
Gliquidone	
Glucagon	
Glutethimide	
Glyceryl trinitrate	Preparations intended for sublingual application
Glycopyrrolate	
Glycopyrronium	
Glymidine	
Golimumab	
Gonadorelin	
Goserelin	
Gramicidins	
Granisetron	
Grepafloxacin	
Griseofulvin	
Guanethidine	
Guanoclor	
Guanoxan	
Hachimycin	
Halazepam	
Halcinonide	
Halofantrine	
Halometasone	
Haloperidol and other 4-substituted derivatives of N-(3-p-fluorobenzoylpropyl) piperidine	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Haloproglin	Preparations intended for dermatological uses, containing not more than 1%
Halothane	
Haloxazolam	
Heparin	Preparations intended for external use only
Heparin calcium	
Heptabarbitalone	
Heptaminol	
Hexamethonium	
Hexamethylmelamine	
Hexapropymate	
Hexobarbitalone	
Hexoestrol	Preparations intended for external application only, containing not more than 0.04%
Histrelin	
Histrelin Acetate	
Homatropine	
Homochlorcyclizine	Preparations intended for external application only; Preparations containing not more than 1% for application in the nose or eye
Hydralazine	
Hydrochlorothiazide	
Hydrocodone	
Hydrocortisone	Preparations intended for external application containing not more than 1%
Hydromorphanol	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Hydromorphone	
Hydroquinone	
Hydroxychloroquine	
Hydroxycinchoninic	
Hydroxyprogesterone	
Hydroxyquinoline	
Hydroxyurea	
Hydroxyzine	
Hygromycin B	
Ibacinabine	
Ibandronic acid	
Ibuprofen	Preparations intended for external application;
	Preparations for oral administration containing not more than 200mg, when used and supplied according to the following conditions:
	Indications: Relief of headache, menstrual pain, backache, muscular and arthritic pain, toothache, and the aches of cold and flu and reduction of fever
	Maximum daily dose: 1.2g
	Maximum supply: 10 days
	The lowest effective dose should be used for the shortest duration necessary to relieve symptoms
	Minimum age: 12 years;
	Oral liquid preparation not more than 100mg/5ml when used and supplied according to the following conditions:
	Indications: Reduction of

<i>First column</i> Active ingredient	<i>Second column</i> Exceptions fever, including post-immunisation pyrexia, and relief of mild to moderate pain such as sore throat, teething pain and toothache, earache, minor aches and sprains Maximum daily dose: 30 mg/kg, up to a maximum of 1.2g Maximum supply: 3 days. The lowest effective dose should be used for the shortest duration necessary to relieve symptoms Minimum age: 6 months
Idarubicin	
Idoxuridine	
Idrocilamide	
Idursulfase	
Ifenprodil	
Ifosfamide	
Iloprost	
Imatinib	
Imidapril	
Imiglucerase	
Imipenem	
Imipramine	
Imiquimod	
Indacaterol	
Indapamide	
Indinavir	
Indium pentetreotide	
Indobufen	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Indomethacin	
Infliximab	
Interferons	
Iodixanol	
Iodine-131	
Ipratropium	
Iprindole	
Iproniazid	
Irbesartan	
Irinotecan	
Isepamicin	
Isoaminile	
Isocarboxazid	
Isoconazole	Preparations intended for external application; Preparations intended for vaginal application
Isoetharine	
Isoflurane	
Isomethadone (isoamidone)	
Isoniazid	
Isoprenaline	
Isopropamide	
Isopyrin	
Isosorbide	
Isothipendyl	Preparations intended for external application only; Preparations containing not more than 1% application in the nose or eye

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Isotretinoin	
Isoxicam	
Isoxsuprine	
Isradipine	
Itopride	
Itraconazole	
Ivabradine	
Ivermectin	
Ixabepilone	
Kanamycin	
Kanendomycin	
Ketamine	
Ketanserin	
Ketazolam	
Ketobemidone	
Ketoconazole	Preparations intended for external application; Preparations intended for vaginal application
Ketoprofen	Preparations for external application
Ketorolac	
Ketotifen	Preparations intended for application to the eye, not exceeding 0.25mg/ml when used and supplied according to the following conditions: Indications: For the short-term treatment of symptoms of allergic conjunctivitis (e.g. itchy or watery eyes) Dosing regimen: Adults, elderly and children (age 3 and older): One drop

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Labetalol	into the affected eye or eyes twice daily (in the morning and evening) Maximum daily dose: 2 drops per affected eye Maximum supply: 10ml Minimum age: 3 years
Lacidipine	
Lafutidine	
Lamivudine	
Lamotrigine	
Lanreotide	
Lansoprazole	
Lanthanum carbonate hydrate	
Lapatinib	
Lapatiniv ditosylate	
Laronidase	
Laropipant	
L-Asparaginase	
Latanoprost	
Laudexium	
Lefetamine	
Leflunomide	
Lenalidomide	
Lenograstim	
Lepirudin	
Lercanidipine	
Letrozole	
Leucovorin	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Leuprorelin	
Levamisole	
Levamphetamine	
Levetiracetam	
Levobunolol	
Levocabastine	Preparations intended for external application only; Preparations containing not more than 1% for application in the nose or eye
Levodopa	
Levofloxacin	
Levomethamphetamine	
Levomethorphan	
Levomoramide	
Levonorgestrel	
Levorphanol	
Levosimendan	
Levothyroxine	
Lidoflazine	
Lignocaine	Preparations intended for external application containing not more than 8%
Linagliptin	
Lincomycin	
Linezolid	
Liothyronine sodium	
Liraglutide	
Lisinopril	
Lisuride	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Lithium carbonate	
Lodoxamide	
Lofentanil	
Lofepamine	
Lomefloxacin	
Lomustine	
Lonazolac	
Lopinavir	
Loprazolam	
Loracarbef	
Lorazepam	
Lormetazepam	
Losartan	
Loteprednol	
Lovastatin	
Loxoprofen	
L-Pyroglutamyl-L-histidyl-L-proline amide	
Lumefantrine	
Luteinising hormone	
Lutropin alpha	
Lymecycline	
Lynoestrenol	
Lypressin	
Lysuride	
Mafenide	
Mangafodipir	
Mannityl hexanitrate	
Mannomustine	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Maprotiline	
Maraviroc	
Mazindol	
Mebanazine	
Mebezonium	
Mebhydrolin	Preparations intended for external application only; Preparations containing not more than 1% for application in the nose or eye
Mebutamate	
Mecamylamine	
Meclastine	Preparations intended for external application only; Preparations containing not more than 1% for application in the nose or eye
Meclofenamic acid	
Meclofenoxate	
Mecloqualone	
Meclozine	Preparations intended for external application only; Preparations containing not more than 1% for application in the nose or eye
Medazepam	
Medigoxin	
Medrogestone	
Medroxyprogesterone	
Mefenamic acid	
Mefenorex	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Mefloquine	Preparations intended for oral administration when supplied for prophylaxis of malaria
Mefruside	
Megestrol	
Meglumine gadoterate	
Melengestrol	
Melitracen	
Meloxicam	
Melphalan	
Memantine	
Menotrophine	
Mepenzolate	
Mephenesin	
Mephentermine	
Mepivacaine	
Meprobamate	
Mepyramine	Preparations intended for external application only; Preparations containing not more than 1% for application in the nose or eye
Mequitazine	Preparations intended for external application only; Preparations containing not more than 1% for application in the nose or eye
Mercaptopurine; derivatives of mercaptopurine	
Meropenem	
Mesalazine	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
MESNA (2-mercaptoethane sulfonate sodium)	
Mesocarb	
Mesoridazine	
Mestanolone	
Mesterolone	
Mestranol	
Metabutethamine	
Meta-Iodobenzylguanidine (I-131)	
Metaraminol	
Metaxalone	
Metazocine	
Metergoline	
Metformin	
Methacycline	
Methadone (amidone)	
Methadyl acetate	
Methallenoestril	
Methandienone	
Methandriol	
Methanthelinium bromide	
Methapyrilene	
Methaqualone	
Metharbitone	
Methcathinone	
Methdilazine	Preparations intended for external application only; Preparations containing not more than 1% for application in the nose or eye

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Methenolone	
Methicillin	
Methimazole	
Methisoprinol	
Methixene	
Methocarbamol	
Methohexitone	
Methoin	
Methoserpidine	
Methotrexate	
Methotrimeprazine	
Methoxamine	
Methoxsalen	
Methoxyphenamine	
Methsuximide	
Methyclothiazide	
Methyl 5-aminolevulinate hydrochloride	
Methylaminoheptane	
Methylamphetamine	
Methyldihydromorphine	
Methyldopa	
Methyldopate	
Methylephedrine	
Methylergometrine	
Methylnaltrexone bromide	
Methylpentynol	
Methylphenidate	
Methylphenobarbitone	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Methylprednisolone	
Methylsulphonal	
Methyltestosterone	
Methylthiouracil	
Methyprylone	
Methysergide	
Metipranolol	
Metoclopramide	
Metolazone	
Metomidate	
Metopon	
Metoprolol	
Metronidazole	
Mexiletine	
Mianserin	
Mibefradril	
Micafungin	
Miconazole	Preparations intended for external application; Preparations intended for vaginal application
Micronomicin	
Midazolam	
Midecamycin	
Midodrine	
Miglitol	
Milrinone	
Miltefosine	
Minaprine	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Minocycline	
Minoxidil	Preparations intended for external application containing not more than 5%
Mirtazapine	
Misoprostol	
Mithramycin	
Mitobronitol	
Mitomycins	
Mitopodozide	
Mitotane	
Mitoxantrone	
Mivacurium	
Mizolastine	
m-Nitrophenol; o-nitrophenol; p-nitrophenol	
Moclobemide	
Moexipril	
Molgramostim	
Molindone	
Mometasone	
Monofluoroacetic acid	
Montelukast	
Morazone	
Morinamide	
Moroctocog alfa	
Moroxydine	
Morphine methylbromide; morphine N-oxide and other pentavalent nitrogen morphine derivatives	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Moxalactam	
Moxifloxacin	
Moxonidine	
Mupirocin	
Muromonab-CD3	
Mustine and any other N-substituted derivatives of di-(2-chloroethyl) amine	
Mycophenolic acid	
Myrophine	
Myrtecaine	
N-[α -methyl-3,4-(methylenedioxy)phenethyl]hydroxylamine (N-hydroxy MDA)	
Nabumetone	
N-Acetylaspartyl glutamic acid sodium salt	
Nadolol	
Nadroparin	
Nafarelin	
Nafcillin	
Naftidrofuryl	
Naftifine	
Nalbuphine	
Nalidixic acid	
Nalorphine	
Naloxone	
Naltrexone	
Nandrolone	
Naproxen	Preparations intended for oral administration, containing not more

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
	than 220 mg of naproxen when supplied according to the following conditions: Indication: For the temporary management of pain and discomfort associated with headache, backache, muscular aches and pains, minor pain of arthritis, toothache, period pain; and reduction of fever such as that associated with the common cold
Naratriptan	
Natalizumab	
Natamycin	
Nateglinide	
N-Benzoyl sulphaniamide	
Nealbarbitone	
Nebivolol	
Nedocromil	
Nefazodone	
Nefopam	
Nelfinavir	
Neosphenamine	
Neomycin	
Neostigmine	
Nepafenac	
Netilmicin	
Nevirapine	
Nialamide	
Niaprazine	
Nicardipine	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Nicergoline	
Nicocodine	
Nicodicodine	
Nicomorphine	
Nicotinic acid	
Nicoumalone	
Nifedipine	
Nifuroxazide	
Nifurzide	
Nikethamide	
Nilotinib	
Nilvadipine	
Nimesulide	
Nimetazepam	
Nimodipine	
Nimorazole	
Niridazole	
Nisoldipine	
Nitrazepam	
Nitrendipine	
Nitric oxide	
Nitrofurantoin	
Nitrofurazone	
Nitromin	
Nitroprusside	
Nitroxoline	
Nizatidine	
Nomegestrol	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Nometasone	
Nomifensine	
Nonacog alfa	
Noracymethadol	
Noradrenaline	Preparations intended for external application or for administration by inhalation; Preparations intended for rectal application; Preparations intended for application to the eye
Noramidopyrine	
Norbuprenorphine	
Norcodeine	
Nordazepam	
Norelgestromin	
Norethandrolone	
Norethisterone	
Norethynodrel	
Norfloxacin	
Norgestimate	
Norgestrel	
Norketamine	
Norlevorphanol	
Normethadone	
Normorphine	
Norpipanone	
Nortriptyline	
Novobiocin	
Noxythiolin	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Nystatin	
Ocriplasmin	
Octacosactrin	
Octocog alfa	
Octreotide	
Oestradiol	
Oestriol	
Oestrone	
Ofatumumab	
Ofloxacin	
Olanzapine	
Oleandomycin	
Olmesartan	
Olodaterol	
Olopatadine	
Olsalazine	
Omalizumab	
Omeprazole	Preparations intended for oral administration, containing not more than 20 mg when supplied according to the following conditions: Indication: For the relief of heartburn symptoms associated with acid reflux Dosing regimen: The initial starting dose is 20 mg daily. When symptoms improve the dose can then be reduced to 10 mg daily, returning to 20mg daily if symptoms return. The lowest effective daily dose should always be

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Ondansetron	
Opipramol	
Opium	
Orciprenaline	
Orlistat	used Maximum dose: 20mg daily Maximum supply: 14 days Minimum age: 18 years
Ornidazole	
Orphenadrine	
Orthocaine	
Oseltamivir	
Oteracil	
Oxaliplatin	
Oxamniquine	
Oxandrolone	
Oxantel	
Oxatomide	Preparations intended for oral administration, containing not more than 120 mg
Oxazepam	
Oxazolam	
Oxcarbazepine	
Oxedrine	
Oxidronic acid	
Oxiracetam	Preparations intended for external application only; Preparations containing not more than 1% for application in the nose or eye

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Oxolinic acid	
Oxomemazine	Preparations intended for external application only; Preparations containing not more than 1% for application in the nose or eye
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	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Pancuronium	
Panitumumab	
Pantoprazole	Preparations intended for oral administration, containing not more than 20mg when supplied according to the following conditions: Indication: For the relief of heartburn symptoms associated with acid reflux Maximum daily dose: 20mg Maximum supply: 14 days Minimum age: 18 years
Paraldehyde	
Paramethadione	
Paramethasone	
Parecoxib	
Pargyline	
Paricalcitol	
Parnaparin	
Paromomycin	
Paroxetine	
Pasireotide	
Pazopanib	
Pecilocin	
Pefloxacin	
Pegaptanib	
Pegfilgrastim	
Peginterferon	
Pegvisomant	
Pemetrexed	
Pemoline	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Pempidine	
Penamecillin	
Penciclovir	
Penethamate	
Penfluridol	
Penicillamine	
Penicillin G; benzylpenicillin	
Penicillin V; phenoxymethylpenicillin	
Pentaerythritol tetranitrate	
Pentamidine	
Pentazocine	
Penthienate	
Pentobarbitone	
Pentolinium	
Pentoxifylline	
Perfluoropropane	
Pergolide	
Perhexiline	
Pericyazine	
Perindopril	
Perphenazine	
Pertuzumab	
Pethidine	
Pethidinic acid	
Phenacaine	
Phenacemide	
Phenacetin	
Phenaglycodol	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Phenazocine	
Phenbenicillin	
Phenbutrazate	
Phencyclidine	
Phendimetrazine	
Phenelzine	
Phenethicillin	
Phenethylamine	
Phenetidylphenacetin	
Pheneturide	
Phenformin	
Phenglutarimide	
Phenindamine	Preparations intended for external application only; Preparations containing not more than 1% for application in the nose or eye
Phenindione	
Pheniramine	Preparations intended for external application only; Preparations containing not more than 1% for application in the nose or eye
Phenmetrazine	
Phenobarbitone	
Phenoperidine	
Phenothiazine	
Phenoxybenzamine	
Phenoxyethylpenicillin	
Phenoxypropazine	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Phenprocoumon	
Phensuximide	
Pentetermine	
Pentolamine	
Phenylbutazone	
Phenylmethyl barbituric acid	
Phenylpropanolamine	
Phenytoin	
Phthalylsulphacetamide	
Phthalylsulphathiazole	
Physostigmine	
Picrotoxin	
Pilocarpine	
Pimecrolimus	
Piminodine	
Pimozide	
Pinazepam	
Pioglitazone	
Pipecuronium	
Pipemidic acid	
Pipenzolate	
Piperacillin	
Piperazine oestrone sulphate	
Piperidolate	
Pipothiazine	
Pipradrol	
Piracetam	
Pirenoxine	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Pirenzepine	
Piribedil	
Piriramide	
Piroxicam	Preparations for external application only
Pirprofen	
Pivmecillinam	
Pizotifen	
Plerixafor	
p-Methoxy- α -methylphenethylamine	
Poldine methylsulphate	
Polidexide	
Polymethylene-bis(trimethylammonium salts	
Polymyxins	
Polyoestradiol	
Polythiazide	
Posaconazole	
Practolol	
Pralatrexate	
Pralidoxime	
Pramipexole	
Prasugrel	
Pravastatin	
Prazepam	
Praziquantel	
Prazosin	
Prednicarbate	
Prednisolone	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Prednisone	
Pregabalin	
Prenoxdiazine	
Prenylamine	
Prilocaine	
Procaine	
Primaquine	
Primidone	
Prindolol	
Probenecid	
Probucol	
Procainamide	
Procaine penicillin	
Procarbazine	
Prochlorperazine	
Procyclidine	
Profenone	
Progesterone	
Proguanil	
Prolintane	
Promazine	
Promestriene	
Promoxolane	
Pronethalol	
Propafenone	
Propanidid	
Propantheline	
Proparacaine	Preparations containing not more than 0.5% for application in the eye

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Propicillin	
Propiomazine	
Propiram	
Propiverine	
Propofol	
Propoxyphene	
Propranolol	
Propylhexedrine	
Propylthiouracil	
Propyromazine	
Proquamezine	
Proquazone	
Prostaglandins	
Protamine sulphate	
Prothionamide;	
Prothipendyl	
Protirelin	
Protriptyline	
Proxymetacaine	
Proxiphylline	
Prucalopride	
Psilocybine	
Pyrathiazine	Preparations intended for external application only; Preparations containing not more than 1% for application in the nose or eye
Pyrazinamide	
Pyridinolcarbamate	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Pyridostigmine	
Pyrimethamine	
Pyritinol	
Pyrovalerone	
Pyrrobutamine	Preparations intended for external application only; Preparations containing not more than 1% for application in the nose or eye
Quetiapine	
Quinagolide	
Quinalbarbitone	
Quinapril	
Quinestradol	
Quinestrol	
Quinethazone	
Quinidine	
Quinine	
Quinupristin	
Rabeprazole	
Racecadotril	
Racemethorphan	
Racemoramide	
Racemorphan	
Radium-223 chloride	
Rafoxanide	
Raloxifene	
Raltegravir	
Raltitrexed	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Ramipril	
Ranibizumab	
Ranitidine	Preparations intended for oral administration, containing not more than 75mg in solid dosage form, or 150mg/10ml in liquid dosage form, when supplied according to the following conditions: Indications: Short-term relief of heartburn, dyspepsia and hyperacidity Maximum daily dose: 300 mg Maximum supply: Up to 2 weeks' duration
Rasburicase	
Raubasine	
Razoxane	
Reboxetine	
Regorafenib	
Remifentanyl	
Repaglinide	
Reserpine	
Retapamulin	
Reteplase	
Retigabine	
Retinoic acid	
Reviparin	
Rhodamine B	
Ribavirin	
Rifamide	
Rifampicin	
Rilmenidine	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Rilpivirine	
Riluzole	
Rimexolone	
Rimiterol	
Risedronic acid	
Risperidone	
Ristocetin	
Ritodrine	
Ritonavir	
Rituximab	
Rivaroxaban	
Rivastigmine	
Rizatriptan	
Rocuronium	
Rofecoxib	
Rolitetraacycline	
Romiplostim	
Ropinirole	
Ropivacaine	
Rosiglitazone	
Rosoxacin	
Rosuvastatin	
Rotigotine	
Roxatidine	
Roxithromycin	
Rupatadine	
Ruxolitinib	
Salazosulphadimidine	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Salmefamol	
Salmeterol	
Santonin	
Saquinavir	
Saxagliptin	
Secbutobarbitone	
Secnidazole	
Secobarbital	
Selegiline	
Selenium sulphide	Preparations for external application containing not more than 2.5%
Sermorelin	
Sertaconazole	Preparations intended for external application; Preparations intended for vaginal application
Sertraline	
Sevelamer	
Sevoflurane	
Sibutramine	
Sildenafil	
Silver sulphadiazine	
Simfibrate	
Simvastatin	
Sirolimus	
Sisomicin	
Sitagliptin	
Sodium apolate	
Sodium aurothiomalate	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Sodium dihydroazapentacene	
Sodium fluoride	Tablets containing not more than 0.016% of sodium fluoride and intended, when chewed, to prevent tooth decay; Dentifrices containing not more than 0.5% of sodium fluoride; Tablets containing not more than 0.016% of sodium fluoride and intended, when chewed, to prevent tooth decay
Sodium iodide [I-131]	
Sodium molybdate	
Sodium oxidronate	
Sodium pertechnetate	
Sodium picosulphate	
Sodium tetracyclol sulphate	
Sodium valproate	
Solifenacin	
Somatostatin	
Somatropin	
Sorafenib	
Sotalol	
Sparfloxacin	
Spectinomycin	
Spiramycin	
Spironolactone	
Stanolone	
Stanozolol	
Stavudine	
Stilboestrol	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Streptokinase	
Streptomycin and its derivatives	
Streptozocin	
Strontium [89Sr]	
Styramate	
Succinylsulphathiazole	
Sufentanil	
Sugammadex	
Sulbactam	
Sulbenicillin	
Sulfabenzamide	
Sulfacytine	
Sulfametopyrazine	
Sulfametrole	
Sulindac	
Sulphabromomethazine	
Sulphacetamide	
Sulphachlorpyridazine	
Sulphadiazine	
Sulphadicramide	
Sulphadimethoxine	
Sulphadimidine	
Sulphadoxine	Preparations intended for oral administration, containing sulphadoxine when supplied for prophylaxis of malaria
Sulphaethidole	
Sulphafurazole	
Sulphaguanidine	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Sulphaloxic acid	
Sulphamerazine	
Sulphamethazine	
Sulphamethizole	
Sulphamethoxazole	
Sulphamethoxydiazine	
Sulphamethoxypyridazine	
Sulphametopyrazine	
Sulphamonomethoxine	
Sulphamoxole	
Sulphanilamide	
Sulphaphenazole	
Sulphapyrazole	
Sulphapyridine	
Sulphaquinoxaline	
Sulphasalazine	
Sulphasomidine	
Sulphathiazole	
Sulphathiourea	
Sulphatolamide	
Sulphaurea	
Sulphinpyrazone	
Sulphomyxin	
Sulphonat; alkyl sulphonals	
Sulpiride	
Sulprostone	
Sultamicillin	
Sulthiame	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Sumatriptan	
Sunitinib	
Suprofen	
Suxamethonium	
Suxethonium bromide	
Syrosingopine	
Tacrine	
Tacrolimus	
Tadalafil	
Tafluprost	
Talampicillin	
Tamoxifen	
Tamsulosin	
Tazarotene	
Tazobactam	
Teclonthiazide	
Tegafur	
Tegaserod	
Teicoplanin	
Telbivudine	
Telithromycin	
Telmisartan	
Temazepam	
Temozolomide	
Temsirolimus	
Tenamfetamine (MDA)	
Tenecteplase	
Teniposide	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Tenocyclidine	
Tenofovir	
Tenonitroazole	
Tenoxicam	
Terazosin	
Terbinafine	Preparations intended for dermatological application, containing not more than 1%
Terconazole	
Terfenadine	
Teriparatide	
Terlipressin	
Tertatolol	
Testosterone	
Tetrabenazine	
Tetracaine	
Tetracosactide	
Tetracyclines	
Tetrahydrocannabinol	
Tetrazepam	
Tetrofosmin	
Thalidomide	
Thallium	
Thebacon	
Thenalidine	Preparations intended for external application only; Preparations containing not more than 1% for application in the nose or eye

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Thenyldiamine	Preparations intended for external application only; Preparations containing not more than 1% for application in the nose or eye
Theofibrate	
Theophylline	
Thiabendazole	
Thiacetazone	
Thialbarbitone	
Thiamazole	
Thiambutosine	
Thiamphenicol	
Thiazinamium methylsulphate	Preparations intended for external application only; Preparations containing not more than 1% for application in the nose or eye
Thiethylperazine	
Thiocarlide	
Thioguanine	
Thiopentone	
Thiopropazate	
Thiopropazine	
Thioridazine	
Thiotepa	
Thiothixene	
Thiouracil; its alkyl derivatives	
Thymosin alpha-1	
Thymoxamine	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
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	Preparations intended for external application; Preparations intended for vaginal application
Tiotropium	
Tirilazad	
Tirofiban	
Tixocortol	
Tizanidine	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Tobramycin	
Tocainide	
Tocilizumab	
Tofenacin	
Tolazamide	
Tolazoline	
Tolbutamide	
Tolcapone	
Tolmetin	
Toloxatone	
Tolperisone	
Tolpropamine	Preparations intended for external application only; Preparations containing not more than 1% for application in the nose or eye
Tolterodine	
Topiramate	
Topotecan	
Toremifene	
Tosufloxacin	
Trabectedin	
Tramadol	
Tranexamic acid	
Tranlycypromine	
Trastuzumab	
Travoprost	
Trazodone	
Treosulphan	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Tretamine	
Tretinoin	
Triacetyloleandomycin	
Triamcinolone	<p>Preparations intended for application to the oral mucosa containing not more than 0.1%, when supplied according to the following conditions:</p> <p style="padding-left: 40px;">Indication: For the treatment of mouth ulcers;</p> <p>Intranasal spray containing not more than 55 mcg/actuation if following criteria are met:</p> <p style="padding-left: 40px;">Indication: Prevention and treatment of allergic rhinitis Maximum daily dose: 220 mcg Maximum supply: 3 months Minimum age: 18 years</p>
Triamterene	
Triaziquone	
Triazolam	
Tribenoside	
Tribromethyl alcohol	
Trichomycin	
Triclofos sodium	
Tricyclamol	
Trienbolone	
Trientine	
Trifluoperazine	
Trifluorothymidine	
Trifluoperidol	
Trifluridine	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Triflusal	
Trihexyphenidyl	
Trimebutine	
Trimegestone	
Trimeperidine	
Trimeprazine	
Trimetaphan	
Trimetazidine	
Trimethoprim	
Trimetrexate	
Trimipramine	
Trimustine	
Tripamide	
Tripeleennamine	Preparations intended for external application only; Preparations containing not more than 1% for application in the nose or eye
Triptorelin	
Tromantadine	
Tropicamide	
Tropisetron	
Trospium	
Trovafloxacin	
Troxidone	
Tubocurarine	
Tybamate	
Tylosin	
Ulipristal	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Unoprostone	
Uramustine	
Urapidil	
Urea	External preparations containing not more than 10%
Ureamycin	
Urethane	
Urokinase	
Ursodeoxycholic acid	
Ustekinumab	
Valaciclovir	
Valdecoxib	
Valganciclovir	
Valproic acid	
Valsartan	
Vancomycin	
Vardenafil	
Varenicline	
Vasopressins	
Vecuronium	
Vemurafenib	
Venlafaxine	
Verapamil	
Vernakalant	
Verteporfin	
Vidarabine	
Vigabatrin	
Vildagliptin	
Viloxazine	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Vinbarbitone	
Vinblastine	
Vincristine	
Vindesine	
Vinflunine	
Vinorelbine	
Vinpocetine	
Vinylbital	
Viomycin	
Virginiamycin	
Voriconazole	
Warfarin	
Xamoterol	
Xipamide	
Xylazine	
Xylometazoline	
Yttrium - 90 chloride	
Zafirlukast	
Zalcitabine	
Zanamivir	
Zidovudine	
Zipeprol	
Ziprasidone	
Zofenopril	
Zolendronic acid	
Zolmitriptan	
Zolpidem	
Zopiclone	

<i>First column</i>	<i>Second column</i>
Active ingredient	Exceptions
Zoxazolamine	
Zuclopenthixol	

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.

PART 3

ACTIVE INGREDIENTS IN PHARMACY-ONLY AND GENERAL SALE
LIST MEDICINES

Acetyl cysteine
Albendazole
Alverine
Ambroxol
Amorolfine
Amyl nitrite
Bambuterol
Benzydamine
Bromhexine
Brompheniramine
Buclizine
Butyl aminobenzoate
Carbinoxamine
Carbocysteine

Cetirizine
Chlorpheniramine
Cinnarizine
Desloratadine
Dexchlorpheniramine
Dicycloverine
Dimenhydrinate
Diphenhydramine
Diphenoxylate
Fexofenadine
Flunarizine
Hyoscine
Levodropropizine
Loperamide
Loratadine
Mebendazole
Mebeverine
Naphazoline
Nicotine
Nitroglycerin
Oxethazaine
Parachlorophenol
Phenyltoloxamine
Pholcodine
Podophyllum resin
Podophyllotoxin
Policresulen
Procaterol
Promethazine
Pseudoephedrine

Salbutamol
 Sodium cromoglycate
 Terbutaline
 Tetrahydrozoline
 Tolnaftate
 Triprolidine
 Tyrothricin

THIRD SCHEDULE

<i>First column</i>	<i>Second column</i>	Regulations 11(1)(d) and 12(b) <i>Third column</i>
Person exempted	Prescription-only medicines to which the exemption applies	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 in so far as is 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 in pursuance of any written law with respect to the medical treatment of their employees	Such prescription-only medicines as may be specified in the relevant written law	The supply — (a) must be for the purpose of enabling them to comply with any requirements made by or in pursuance of any written law; and (b) is subject to such conditions and is to be made in such circumstances as may be specified in the relevant written law

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- | | | | |
|----|---|---|---|
| 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 — |
| | | | <p>(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;</p> <p>(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</p> <p>(c) must keep proper records of the IDC’s administration of the prescription-only medicines</p> |

FOURTH SCHEDULE

Regulation 20(3)

<i>First column</i>	<i>Second column</i>
Substance	Term to be used
1. Tartazine	tartrazine (Code E102) tartrazine (Code 102) tartrazine (Code FD and C Yellow No. 5)
2. Benzoic acid	benzoic acid benzoic acid (Code E210)

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-
- | | | |
|----|-----------------|--|
| 3. | Sodium benzoate | sodium benzoate
sodium benzoate (Code E211) |
|----|-----------------|--|

FIFTH SCHEDULE

Regulation 20(4)

CAUTIONARY INFORMATION TO BE LABELLED ON THERAPEUTIC PRODUCTS

<i>First column</i>	<i>Second column</i>
Therapeutic product	Cautionary information
1. Therapeutic product containing aspirin or acetylsalicylic acid for oral administration	Caution: Not to be given to persons below the age of 16 years except under the direction of a doctor.
2. Therapeutic product containing any of the following substances for oral administration:	Caution: This may cause drowsiness. If affected, do not drive or operate machinery.
(a) Diphenoxylate	
(b) Loperamide	
(c) The following anti-histamine substances:	
Antazoline	
Azatadine	
Bamipine	
Bromodiphenhydramine	
Bromopheniramine	
Buclizine	
Carbinoxamine	
Chlorcyclizine	
Chlorpheniramine	
Cinnarizine	
Clemastine	
Clemizole	
Cyclizine	
Cyproheptadine	
Dimethpyrindene	

Diphenhydramine
Diphenylpyraline
Doxylamine
Embramine
Flunarizine
Homochlorcyclizine
Isothipendyl
Levocabastine
Mebhydrolin
Meclastine
Meclozine
Mepyramine
Mequitazine
Methdilazine
Oxatomide
Oxomemazine
Phenindamine
Pheniramine
Phenyltoloxamine
Promethazine
Pyrathiazine
Pyrrobutamine
Thenalidine
Thenyldiamine
Thiazinamium
Tolpropamine
Tripeleennamine
Triprolidine

SIXTH SCHEDULE

Regulation 23(2) and (6)

PART 1

<p>REPUBLIC OF SINGAPORE HEALTH SCIENCES AUTHORITY HEALTH PRODUCTS (THERAPEUTIC PRODUCTS) REGULATIONS</p> <p>DECLARATION ON PATENT RELATED INFORMATION FOR APPLICATION FOR REGISTRATION OF A THERAPEUTIC PRODUCT</p>	
Application No (for HSA use only):	
SECTION 1: APPLICANT PARTICULARS	
Name	_____
Address	_____
SECTION 2: PRODUCT PARTICULARS	
Proprietary Name	_____
Active Substance(s) and Strength	_____
Dosage Form	_____
SECTION 3: APPLICATION CATEGORY	
Application Category (<i>check one box</i>)*	
<input type="checkbox"/>	Category A1 (Proceed to Section 4) Refers to an application where no patent is in force in respect of the therapeutic product to which the application relates.
<input type="checkbox"/>	Category A2 (Proceed to Section 5) Refers to an application where —
	<p>(a) a patent is in force in respect of the therapeutic product to which the application relates; and</p> <p>(b) the applicant is either the proprietor of the patent or, if the applicant is not the proprietor of the patent, the proprietor has consented to or acquiesced in the grant of the registration.</p>

- Category A3 (Proceed to Section 6)
Refers to an application where —
- (a) a patent is in force in respect of the therapeutic product to which the application relates;
 - (b) the applicant is not the proprietor of the patent;
 - (c) the proprietor has not consented to nor acquiesced in the grant of the registration; and
 - (d) the applicant is requesting for registration to be granted after the patent expires.
- Such an application may not be made earlier than 18 months before the patent expires.
- Category B (Proceed to Section 7)
Refers to an application where —
- (a) a patent is in force in respect of the therapeutic product to which the application relates;
 - (b) the applicant is not the proprietor of the patent;
 - (c) the proprietor has not consented to nor acquiesced in the grant of the registration; and
 - (d) in the opinion and to the best belief of the applicant, the patent is invalid or will not be infringed by the doing of the act for which the registration is sought.

SECTION 4: INFORMATION FOR CATEGORY A1 APPLICATIONS

I, the applicant/the authorised agent of the applicant on behalf of the applicant, declare that —

There is no patent under the Patents Act (Cap. 221) in force in respect of the product stated in Section 2 on the date of this declaration.

SECTION 5: INFORMATION FOR CATEGORY A2 APPLICATIONS

I, the applicant/the authorised agent of the applicant on behalf of the applicant, declare that — (*check one box*)

- A patent under the Patents Act is in force in respect of the product stated in Section 2 on the date of this declaration.
I am the proprietor of the patent.
The Singapore Patent No. for the patent is _____.

A patent under the Patents Act is in force in respect of the product stated in Section 2 on the date of this declaration.

I am not the proprietor of the patent but the proprietor has consented to or acquiesced in the grant of the registration for the product stated in Section 2 to me.

The name and address of the proprietor of the patent or his authorised agent are _____.

The Singapore Patent No. for the patent is _____.

SECTION 6: INFORMATION FOR CATEGORY A3 APPLICATIONS

I, the applicant/the authorised agent of the applicant on behalf of the applicant, declare that —

A patent under the Patents Act is in force in respect of the product stated in Section 2 on the date of this declaration.

I am not the proprietor of the patent and the proprietor has not consented to nor acquiesced in the grant of the registration for the product stated in Section 2 to me.

I am requesting for the grant of the registration after the patent expires.

I am making the application not earlier than 18 months before the patent expires.

The name and address of the proprietor of the patent or his authorised agent are _____.

The Singapore Patent No. for the patent is _____.

The patent will expire on _____ (dd/mm/yyyy), which is __ months from the date of my registration application.

SECTION 7: INFORMATION FOR CATEGORY B APPLICATIONS

I, the applicant/the authorised agent of the applicant on behalf of the applicant, declare that —

A patent under the Patents Act is in force in respect of the product stated in Section 2 on the date of this declaration.

I am not the proprietor of the patent and the proprietor has not consented to nor acquiesced in the grant of the registration for the product stated in Section 2 to me.

In my opinion and to my best belief, the patent is invalid.

The name and address of the proprietor of the patent or his authorised agent are _____.

The Singapore Patent No. for the patent is _____.

The patent will expire on _____ (dd/mm/yyyy).

SECTION 8: DECLARATION

I am duly authorised by the applicant to make this declaration on behalf of the applicant, and enclose with this declaration form evidence of such authorisation[#].

I, the applicant/the authorised agent of the applicant on behalf of the applicant, declare that all information furnished in this form is true.

I am aware that the Health Sciences Authority may rely on, and need not be concerned to enquire into the truth of, any statement made in this declaration form.

I am aware that a false declaration is an offence under the Health Products Act (Cap. 122D).

I further undertake to notify the Health Sciences Authority of any change in the information furnished in this form.

Name: _____

Designation: _____

Signature and Date:

Applicant's Stamp:

[#] Please enclose appropriate evidence of authorisation. Delete this statement if applicant is a natural person making the application personally.

PART 2

REPUBLIC OF SINGAPORE
HEALTH SCIENCES AUTHORITY
HEALTH PRODUCTS (THERAPEUTIC PRODUCTS) REGULATIONS

NOTICE TO PROPRIETOR OF PATENT

Date: _____

Name and Address of Proprietor of Patent: _____

Dear Sir

Notice under regulation 23(6)(a) of the Health Products (Therapeutic Products) Regulations

According to regulation 23(6)(a) of the Health Products (Therapeutic Products) Regulations and as required by the Health Sciences Authority (HSA), I notify you that the following application for a product licence has been made to the HSA:

Registration Application Number: _____

Product Name:

Active Substance(s) and Strength: _____

Dosage Form:

Date of Filing of Registration Application: _____

Patent Number and Expiry Date of the relevant Patent: _____

2. In my opinion and to the best of my belief, the above-mentioned patent is invalid or will not be infringed by the doing of the act for which the registration is sought.

[Name and signature of applicant or his authorised agent]

Copy to:

Health Sciences Authority

[Acknowledgement and date of receipt by proprietor of patent]

SEVENTH SCHEDULE

Regulations 42(2), 61 to 64 and 68

FEEs

<i>First column</i>	<i>Second column</i>
Description of fee	Fee payable

EIGHTH SCHEDULE

Regulation 52(1)(b)

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