**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*);

(*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

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;

(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;

(*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 —

(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

(*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;

(*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 —

(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 futher 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 —

(*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;

(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:

(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 pararagraph (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 pararagraph (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;

(*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;

(*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:

Allobarbital

Alprazolam

Amfepramone

Aminorex

Amobarbital

Barbital

Bromazepam

Brotizolam

Butalbital

Butobarbital

Camazepam

Cathine

Chlordiazepoxide

Clobazam

Clonazepam

Clorazepate

Clotiazepam

Cloxazolam

Cyclobarbital

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

| *First column* | *Second column* |
|---|---|
| Active ingredient | Exceptions |
| (±)-4-ethyl-2, 5-dimethoxy-∝-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; |

| *First column* | *Second column* |
|---|---|
| Active ingredient | Exceptions |
| | Preparations containing not more than 1% for application in the nose or eye |
| 4-Cyano-1-methyl-4-phenylpiperidine | |
| 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 | |

| *First column* | *Second column* |
|---|---|
| Active ingredient | Exceptions |
| Acitretin | |
| Acrivastine | |
| Actinomycins | |
| Acyclovir | Preparations for external application only, not exceeding 5% for treatment of cold sore<br>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 | |

| *First column* | *Second column* |
| --- | --- |
| Active ingredient | Exceptions |
| Alfentanil | |
| Alfuzosin | |
| Algestone | |
| Alglucosidase alfa | |
| Aliskiren | |
| Allobarbitone | |
| Allopurinol | |
| Allylisopropylacetylurea | |
| Allyloestrenol | |
| Allylprodine | |
| Alminoprofen | |
| Almitrine | |
| Alosetron | |
| Alphacalcidol | |
| Alphacetylmethadol | |
| Alphachloralose | |
| Alphadolone | |
| Alphameprodine | |
| Alphamethadol | |
| Alphaprodine | |
| Alphaxalone | |
| Alprazolam | |
| Alprenolol | |
| Alprostadil | |
| Alseroxylon | |
| Alteplase | |
| Altretamine | |
| Amantadine | |

| *First column* | *Second column* |
|---|---|
| Active ingredient | Exceptions |
| Ambenonium | |
| Ambuside | |
| Ambutonium | |
| Ametazole | |
| Amethocaine | |
| Amfepramone | |
| Amidopyrine | |
| Amifostine | |
| Amikacin | |
| Amiloride | |
| Amineptine | |
| Aminocaproic acid | |
| Aminoglutethimide | |
| Aminophylline | |
| Aminopterin | |
| Aminorex | |
| Amiodarone | |
| Amisulpride | |
| Amitriptyline | |
| Amlodipine | |
| Ammonium lactate | |
| Amoxycillin | |
| Amphetamine | |
| Amphomycin | |
| Amphotericin B | |
| Ampicillin | |
| Amprenavir | |
| Amrinone | |

| *First column* | *Second column* |
|---|---|
| Active ingredient | Exceptions |
| Amsacrine (M-AMSA) | |
| Amylobarbitone | |
| Amylocaine | |
| Anagrelide | |
| Anastrozole | |
| Ancrod | |
| Androsterone | |
| Angiotensin amide | |
| Anidulafungin | |
| Anileridine | |
| Anistreplase | |
| Antazoline | Preparations intended for external application only;<br>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 | |

| *First column* | *Second column* |
|---|---|
| Active ingredient | Exceptions |
| Artesunate | |
| Articaine | |
| Asenapine | |
| Aspoxicillin | |
| Astemizole | |
| Atazanavir | |
| Atenolol | |
| Atomoxetine | |
| Atorvastatin | |
| Atosiban | |
| Atovaquone | |
| Atracurium | |
| Atropine | |
| Auranofin | |
| Axitinib | |
| Azacitidine | |
| Azacyclonol | |
| Azaperone | |
| Azapropazone | |
| Azasetron | |
| Azatadine | Preparations intended for external application only;<br>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:<br>Indications: Mild to Moderate |

| *First column* | *Second column* |
|---|---|
| Active ingredient | Exceptions |
| | Acne Vulgaris<br>Maximum daily dose: Apply to the affected area twice daily<br>Maximum supply: 30g<br>Minimum age: 12 years |
| Azelastine | |
| Azidamphenicol | |
| Azidocillin | |
| Azilsartan | |
| Azithromycin | |
| Aztreonam | |
| Bacampicillin | |
| Bacitracin | |
| Baclofen | |
| Bambermycin | |
| Bamipine | Preparations intended for external application only;<br>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:<br>Indications: Prevention and treatment of allergic rhinitis.<br>Maximum daily dose: 200 mcg/nostril |

| *First column* | *Second column* |
|---|---|
| Active ingredient | Exceptions |
| | Maximum supply: up to 3 months' duration<br>Minimum age: 18 years |
| Befunolol | |
| Bekanamycin | |
| Belimumab | |
| Bemegride | |
| Benactyzine; its quarternary compounds | |
| Benapryzine | |
| Benazepril | |
| Bendamustine hydrochloride | |
| Bendrofluazide | |
| Benethamine penicillin | |
| Benfluorex | |
| Benoxaprofen | |
| Benperidol | |
| Benserazide | |
| Benzamidosalicylic acid | |
| Benzathine penicillin | |
| Benzbromarone | |
| Benzethidine | |
| Benzhexol | |
| Benzilonium | |
| Benzocaine | Preparations intended for external application only, containing not more than 1% |
| Benzoctamine | |
| Benzoestrol | Preparations intended for external application only, containing not more than 0.04% |

| *First column* | *Second column* |
|---|---|
| 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;<br>Preparations for vaginal application |
| Bimatoprost | |
| Biperiden | |

| *First column* | *Second column* |
|---|---|
| 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;<br>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:<br>Indications: Prevention and treatment of allergic rhinitis<br>Maximum daily dose: 200 mcg/nostril<br>Maximum supply: up to 3 months' duration |

| *First column* | *Second column* |
| --- | --- |
| 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 | |
| Butanilicaine | |
| Butizide | |
| Butobarbitone | |
| Butoconazole | |
| Butriptyline | |
| Butropium bromide | |
| Butylchloral hydrate | |
| Cabazitaxel | |
| Cabergoline | |
| Cabimicina | |

| *First column* | *Second column* |
|---|---|
| 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 | |

| *First column* | *Second column* |
| --- | --- |
| 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 | |

| *First column* | *Second column* |
|---|---|
| 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;<br>Preparations containing not more than 1% for application in the nose or eye |
| Chlordiazepoxide | |
| Chlormadinone | |
| Chlormerodrin | |

| *First column* | *Second column* |
|---|---|
| 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 | |

| *First column* | *Second column* |
|---|---|
| Active ingredient | Exceptions |
| Cimetidine | Preparations intended for oral administration when supplied according to the following conditions:<br>Indications:<br>(a) Short-term relief of heartburn, dyspepsia and hyperacidity; and<br>(b) Prophylactic management of nocturnal heartburn<br>Maximum daily dose:<br>(a) 200 mg; and<br>(b) 100mg ( as a single night-time dose)<br>Maximum supply:<br>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 |

| *First column* | *Second column* |
|---|---|
| Active ingredient | Exceptions |
| | application only;<br>Preparations containing not more than 1% for application in the nose or eye |
| Clemizole | Preparations intended for external application only;<br>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 | |

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

| *First column* | *Second column* |
|---|---|
| Active ingredient | Exceptions |
| Crizotinib | |
| Cropropamide | |
| Crotethamide | |
| Cyclandelate | |
| Cyclarbamate | |
| Cyclizine | Preparations intended for external application only;<br>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 | |

| *First column* | *Second column* |
| --- | --- |
| 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 | |
| Demoxytocin | |
| Denosumab | |
| Deoxycortone | |
| Deptropine | |
| Deserpidine | |

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

| *First column* | *Second column* |
|---|---|
| Active ingredient | Exceptions |
| Diazepam | |
| Diazoxide | |
| Dibekacin | |
| Dibenzepin | |
| Dibucaine | |
| Dichloralphenazone | |
| Dichlorophenarsine | |
| Dichlorphenamide | |
| Diclofenac | Preparations intended for external application, containing diclofenac diethylammonium salt equivalent to not more than 1%;<br>Preparations for oral administration, containing not more than 12.5 mg when supplied according to the following conditions:<br>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 |
| Dicloxacillin | |
| Didanosine | |
| Dienoestrol | |
| Dienogest | |
| Diethanolamine fusidate | |
| Diethylcarbamazine | |
| Diethylthiambutene | |
| Difenoxin | |
| Diflucortolone | |

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

| *First column* | *Second column* |
|---|---|
| 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;<br>Preparations containing not more than 1% for application in the nose or eye |
| Dipipanone | |
| Dipivefrin | |
| Diprophylline | |
| Dipyridamole | |
| Dipyrone | |
| Dirithromycin | |
| Disopyramide | |
| Distigmine | |
| Disulfiram | |
| Disulphamide | |
| Dithienylallylamines; dithienyl-alkylallylamines | |

| *First column* | *Second column* |
|---|---|
| Active ingredient | Exceptions |
| Dobutamine | |
| Docetaxel | |
| Domperidone | 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:<br>Indications: Relief of postprandial symptoms of excessive fullness, nausea, epigastric bloating and belching occasionally accompanied by epigastric discomfort and heartburn.<br>Maximum daily dose: 30 mg<br>Maximum supply: 14 days<br>Minimum age: 12 years |
| Donepezil | |
| Dopamine | |
| Doripenem | |
| Dorzolamide | |
| Dothiepin | |
| Doxapram | |
| Doxazosin | |
| Doxepin | |
| Doxofylline | |
| Doxorubicin | |
| Doxycycline | |
| Doxylamine | Preparations intended for external application only;<br>Preparations containing not more than 1% for application in the nose or eye |

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

| *First column* | *Second column* |
|---|---|
| Active ingredient | Exceptions |
| | or eye |
| Embutramide | |
| Emedastine | |
| Emedastine | |
| Emepronium | |
| 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 | |
| Epithiazide | |
| Eplerenone | |
| Epoetin Alfa | |
| Epoetin Beta | |
| Epoprostenol | |
| Eprosartan | |

| *First column* | *Second column* |
|---|---|
| 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 | |
| Ethinyloestradiol | |

| *First column* | *Second column* |
|---|---|
| Active ingredient | Exceptions |
| Ethionamide | |
| Ethisterone | |
| Ethoglucid | |
| Ethoheptazine | |
| Ethopropazine | |
| Ethosuximide | |
| Ethotoin | |
| Ethyl biscoumacetate | |
| Ethyl loflazepate | |
| Ethyl p-piperidinoacetylaminobenzoate | |
| Ethylacetanilide | |
| Ethylmorphine | |
| Ethylnoradrenaline | |
| Ethyloestrenol | |
| Ethylstibamine | |
| Ethynodiol | |
| Etidronic acid | |
| Etilamfetamine | |
| Etodolac | |
| Etofenamate | |
| Etofibrate | |
| Etofylline clofibrate | |
| Etomidate | |
| Etonitazene | |
| Etonogestrel | |
| Etoposide | |
| Etoricoxib | |
| Etorphine | |

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

| *First column* | *Second column* |
|---|---|
| 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;<br>Preparations intended for vaginal application |
| Flucytosine | |
| Fludarabine phosphate | |
| Fludiazepam | |
| Fludrocortisone | |
| Flufenamic acid | |

| *First column* | *Second column* |
| --- | --- |
| 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 | |

| *First column* | *Second column* |
|---|---|
| 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 | |
| Fosfomycin | |
| Fosinopril | |
| Fotemustine | |
| Framycetin | |
| Frusemide | |
| Ftorafur | |
| Fulvestrant | |
| Fumagillin | |
| Furaltadone | |
| Furazolidone | |
| Fusafungine | |
| Fusidic acid | |

| *First column* | *Second column* |
|---|---|
| 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 | |

| *First column* | *Second column* |
|---|---|
| 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 | |

| *First column* | *Second column* |
|---|---|
| Active ingredient | Exceptions |
| Haloprogin | Preparations intended for dermatological uses, containing not more than 1% |
| Halothane | |
| Haloxazolam | |
| Heparin | Preparations intended for external use only |
| Heparin calcium | |
| Heptabarbitone | |
| Heptaminol | |
| Hexamethonium | |
| Hexamethylmelamine | |
| Hexapropymate | |
| Hexobarbitone | |
| Hexoestrol | Preparations intended for external application only, containing not more than 0.04% |
| Histrelin | |
| Histrelin Acetate | |
| Homatropine | |
| Homochlorcyclizine | Preparations intended for external application only;<br>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% |
| Hydromorphinol | |

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

| *First column* | *Second column* |
| --- | --- |
| Active ingredient | 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<br>Maximum daily dose:<br>30 mg/kg, up to a maximum of 1.2g<br>Maximum supply: 3 days. The lowest effective dose should be used for the shortest duration necessary to relieve symptoms<br>Minimum age: 6 months |
| Idarubicin | |
| Idoxuridine | |
| Idrocilamide | |
| Idursulfase | |
| Ifenprodil | |
| Ifosfamide | |
| Iloprost | |
| Imatinib | |
| Imidapril | |
| Imiglucerase | |
| Imipenem | |
| Imipramine | |
| Imiquimod | |
| Indacaterol | |
| Indapamide | |
| Indinavir | |
| Indium pentetreotide | |
| Indobufen | |

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

| *First column* | *Second column* |
|---|---|
| Active ingredient | Exceptions |
| Isotretinoin | |
| Isoxicam | |
| Isoxsuprine | |
| Isradipine | |
| Itopride | |
| Itraconazole | |
| Ivabradine | |
| Ivermectin | |
| Ixabepilone | |
| Kanamycin | |
| Kanendomycin | |
| Ketamine | |
| Ketanserin | |
| Ketazolam | |
| Ketobemidone | |
| Ketoconazole | Preparations intended for external application;<br>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:<br>Indications: For the short-term treatment of symptoms of allergic conjunctivitis (e.g. itchy or watery eyes)<br>Dosing regimen:<br>Adults, elderly and children (age 3 and older): One drop |

| *First column* | *Second column* |
| --- | --- |
| Active ingredient | Exceptions |
| | into the affected eye or eyes twice daily (in the morning and evening)<br>Maximum daily dose:<br>2 drops per affected eye<br>Maximum supply: 10ml<br>Minimum age: 3 years |
| Labetalol | |
| 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 | |

| *First column* | *Second column* |
|---|---|
| Active ingredient | Exceptions |
| Leuprorelin | |
| Levamisole | |
| Levamphetamine | |
| Levetiracetam | |
| Levobunolol | |
| Levocabastine | Preparations intended for external application only;<br>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 | |

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

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

| *First column* | *Second column* |
|---|---|
| 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;<br>Preparations containing not more than 1% for application in the nose or eye |
| Mequitazine | Preparations intended for external application only;<br>Preparations containing not more than 1% for application in the nose or eye |
| Mercaptopurine; derivatives of mercaptopurine | |
| Meropenem | |
| Mesalazine | |

| *First column* | *Second column* |
|---|---|
| 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;<br>Preparations containing not more than 1% for application in the nose or eye |

| *First column* | *Second column* |
|---|---|
| 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 | |

| *First column* | *Second column* |
|---|---|
| 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;<br>Preparations intended for vaginal application |
| Micronomicin | |
| Midazolam | |
| Midecamycin | |
| Midodrine | |
| Miglitol | |
| Milrinone | |
| Miltefosine | |
| Minaprine | |

| *First column* | *Second column* |
|---|---|
| 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 | |

| *First column* | *Second column* |
|---|---|
| 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 |

| *First column* | *Second column* |
| --- | --- |
| Active ingredient | Exceptions |
| | than 220 mg of naproxen when supplied according to the following conditions:<br>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 sulphanilamide | |
| Nealbarbitone | |
| Nebivolol | |
| Nedocromil | |
| Nefazodone | |
| Nefopam | |
| Nelfinavir | |
| Neoarsphenamine | |
| Neomycin | |
| Neostigmine | |
| Nepafenac | |
| Netilmicin | |
| Nevirapine | |
| Nialamide | |
| Niaprazine | |
| Nicardipine | |

| *First column* | *Second column* |
|---|---|
| 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 | |

| *First column* | *Second column* |
|---|---|
| Active ingredient | Exceptions |
| Nometasone | |
| Nomifensine | |
| Nonacog alfa | |
| Noracymethadol | |
| Noradrenaline | Preparations intended for external application or for administration by inhalation;<br>Preparations intended for rectal application;<br>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 | |

| *First column* | *Second column* |
|---|---|
| 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:<br>Indication: For the relief of heartburn symptoms associated with acid reflux<br>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 |

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

| *First column* | *Second column* |
|---|---|
| Active ingredient | Exceptions |
| Oxolinic acid | |
| Oxomemazine | Preparations intended for external application only;<br>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 | |

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

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

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

| *First column* | *Second column* |
|---|---|
| Active ingredient | Exceptions |
| Phenprocoumon | |
| Phensuximide | |
| Phentermine | |
| Phentolamine | |
| 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 | |

| *First column* | *Second column* |
|---|---|
| Active ingredient | Exceptions |
| Pirenzepine | |
| Piribedil | |
| Piritramide | |
| Piroxicam | Preparations for external application only |
| Pirprofen | |
| Pivmecillinam | |
| Pizotifen | |
| Plerixafor | |
| p-Methoxy-∝-methylphenethylamine | |
| Poldine methylsulphate | |
| Polidexide | |
| Polymethylene-bistrimethylammonium salts | |
| Polymyxins | |
| Polyoestradiol | |
| Polythiazide | |
| Posaconazole | |
| Practolol | |
| Pralatrexate | |
| Pralidoxime | |
| Pramipexole | |
| Prasugrel | |
| Pravastatin | |
| Prazepam | |
| Praziquantel | |
| Prazosin | |
| Prednicarbate | |
| Prednisolone | |

| *First column* | *Second column* |
|---|---|
| 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 |

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

| *First column* | *Second column* |
|---|---|
| Active ingredient | Exceptions |
| Pyridostigmine | |
| Pyrimethamine | |
| Pyritinol | |
| Pyrovalerone | |
| Pyrrobutamine | Preparations intended for external application only;<br>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 | |

| *First column* | *Second column* |
|---|---|
| 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:<br>Indications: Short-term relief of hearburn, dyspepsia and hyperacidity<br>Maximum daily dose: 300 mg<br>Maximum supply: Up to 2 weeks' duration |
| Rasburicase | |
| Raubasine | |
| Razoxane | |
| Reboxetine | |
| Regorafenib | |
| Remifentanil | |
| Repaglinide | |
| Reserpine | |
| Retapamulin | |
| Reteplase | |
| Retigabine | |
| Retinoic acid | |
| Reviparin | |
| Rhodamine B | |
| Ribavirin | |
| Rifamide | |
| Rifampicin | |
| Rilmenidine | |

| *First column* | *Second column* |
|---|---|
| Active ingredient | Exceptions |
| Rilpivirine | |
| Riluzole | |
| Rimexolone | |
| Rimiterol | |
| Risedronic acid | |
| Risperidone | |
| Ristocetin | |
| Ritodrine | |
| Ritonavir | |
| Rituximab | |
| Rivaroxaban | |
| Rivastigmine | |
| Rizatriptan | |
| Rocuronium | |
| Rofecoxib | |
| Rolitetracycline | |
| Romiplostim | |
| Ropinirole | |
| Ropivacaine | |
| Rosiglitazone | |
| Rosoxacin | |
| Rosuvastatin | |
| Rotigotine | |
| Roxatidine | |
| Roxithromycin | |
| Rupatadine | |
| Ruxolitinib | |
| Salazosulphadimidine | |

| *First column* | *Second column* |
|---|---|
| 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;<br>Preparations intended for vaginal application |
| Sertraline | |
| Sevelamer | |
| Sevoflurane | |
| Sibutramine | |
| Sildenafil | |
| Silver sulphadiazine | |
| Simfibrate | |
| Simvastatin | |
| Sirolimus | |
| Sisomicin | |
| Sitagliptin | |
| Sodium apolate | |
| Sodium aurothiomalate | |

| *First column* | *Second column* |
|---|---|
| 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;<br>Dentifrices containing not more than 0.5% of sodium fluoride;<br>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 tetracedyl sulphate | |
| Sodium valproate | |
| Solifenacin | |
| Somatostatin | |
| Somatropin | |
| Sorafenib | |
| Sotalol | |
| Sparfloxacin | |
| Spectinomycin | |
| Spiramycin | |
| Spironolactone | |
| Stanolone | |
| Stanozolol | |
| Stavudine | |
| Stilboestrol | |

| *First column* | *Second column* |
|---|---|
| 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 | |

| *First column* | *Second column* |
|---|---|
| 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 | |
| Sulphonal; alkyl sulphonals | |
| Sulpiride | |
| Sulprostone | |
| Sultamicillin | |
| Sulthiame | |

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

| *First column* | *Second column* |
|---|---|
| Active ingredient | Exceptions |
| Tenocyclidine | |
| Tenofovir | |
| Tenonitrozole | |
| 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;<br>Preparations containing not more than 1% for application in the nose or eye |

| *First column* | *Second column* |
|---|---|
| Active ingredient | Exceptions |
| Thenyldiamine | Preparations intended for external application only;<br>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;<br>Preparations containing not more than 1% for application in the nose or eye |
| Thiethylperazine | |
| Thiocarlide | |
| Thioguanine | |
| Thiopentone | |
| Thiopropazate | |
| Thioproperazine | |
| Thioridazine | |
| Thiotepa | |
| Thiothixene | |
| Thiouracil; its alkyl derivatives | |
| Thymosin alpha-1 | |
| Thymoxamine | |

| *First column* | *Second column* |
|---|---|
| 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;<br>Preparations intended for vaginal application |
| Tiotropium | |
| Tirilazad | |
| Tirofiban | |
| Tixocortol | |
| Tizanidine | |

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

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

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

| *First column* | *Second column* |
|---|---|
| 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 | |

| *First column* | *Second column* |
|---|---|
| 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 | |

| *First column* | *Second column* |
|---|---|
| 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
Dexchloirpheniramine
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

Regulations 11(1)(*d*) and 12(*b*)

| | *First column* | *Second column* | *Third column* |
|---|---|---|---|
| | 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 —<br>(*a*) must be for the purpose of enabling them to comply with any requirements made by or in pursuance of any written law; and<br>(*b*) is subject to such conditions and is to be made in such circumstances as may be specified in the relevant written law |

| | | | |
|---|---|---|---|
| 3. | An Independent Duty Corpsman ("IDC") deployed on Republic of Singapore Navy ("RSN") vessels who has been authorised by the Chief Navy Medical Officer to administer prescription-only medicines | All prescription-only medicines listed in the IDC Medications List approved by the Chief Navy Medical Officer | An IDC —<br>(*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;<br>(*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<br>(*c*) must keep proper records of the IDC's administration of the prescription-only medicines |

## FOURTH SCHEDULE

Regulation 20(3)

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

| | | |
|---|---|---|
| 3. | Sodium benzoate | sodium benzoate<br>sodium benzoate (Code E211) |

## FIFTH SCHEDULE

Regulation 20(4)

### CAUTIONARY INFORMATION TO BE LABELLED ON THERAPEUTIC PRODUCTS

| | *First column*<br>Therapeutic product | *Second column*<br>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:<br>(*a*) Diphenoxylate<br>(*b*) Loperamide<br>(*c*) The following anti-histamine substances:<br>Antazoline<br>Azatadine<br>Bamipine<br>Bromodiphenhydramine<br>Bromopheniramine<br>Buclizine<br>Carbinoxamine<br>Chlorcyclizine<br>Chlorpheniramine<br>Cinnarizine<br>Clemastine<br>Clemizole<br>Cyclizine<br>Cyproheptadine<br>Dimethpyrindene | Caution: This may cause drowsiness. If affected, do not drive or operate machinery. |

| |
|---|
| 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 |
| Tripelennamine |
| Triprolidine |

# SIXTH SCHEDULE

Regulation 23(2) and (6)

## PART 1

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

DECLARATION ON PATENT RELATED INFORMATION FOR APPLICATION FOR REGISTRATION OF A THERAPEUTIC PRODUCT

**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 *(check one box)**

☐ 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.

☐ Category A2 (Proceed to Section 5)

Refers to an application where —

(*a*) a patent is in force in respect of the therapeutic product to which the application relates; and

(*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.

☐ 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 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

| *First column* | *Second column* |
|---|---|
| Description of fee | Fee payable |
| | |

## EIGHTH SCHEDULE

Regulation 52(1)(*b*)

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