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First published in the Government Gazette, Electronic Edition, on 15th July 2016 at 5:00 pm.

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**No. S 329**

**HEALTH PRODUCTS ACT  
(CHAPTER 122D)**

**HEALTH PRODUCTS (THERAPEUTIC PRODUCTS)  
REGULATIONS 2016**

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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:

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PART 1  
PRELIMINARY

**Citation and commencement**

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

**Definitions**

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

“acute hospital service”, “ambulatory surgical centre service”, “assisted reproduction service”, “blood banking service”, “community hospital service”, “contingency care service”, “nuclear medicine service”, “outpatient dental service”, “outpatient medical service”, “outpatient renal dialysis service” and “radiological service” have the meanings given by paragraph 2 of the First Schedule to the Healthcare Services Act 2020;

*[S 436/2023 wef 26/06/2023]*

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

- (a) orally;
- (b) by injection or by introduction into the body in any other way; or
- (c) by external application, whether by direct contact with the body or not;

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

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

- (b) where the active ingredient is not described in a monograph in any specified publication, its international non-proprietary name; or
- (c) where paragraph (a) or (b) is not applicable, the accepted scientific name or other name descriptive of the true nature of the active ingredient;

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

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

“approved conveyance”, “approved permanent premises” and “permanent premises” have the meanings given by section 2(1) of the Healthcare Services Act 2020;

*[S 436/2023 wef 26/06/2023]*

“Authority’s website” means the Authority’s Internet website at <http://www.hsa.gov.sg>;

“business name”, in relation to a healthcare service licensee, means the name under which the healthcare service licensee is authorised by a licence under the Healthcare Services Act 2020 to carry on the business of providing a licensable healthcare service;

*[S 436/2023 wef 26/06/2023]*

“codeine cough preparation” means a therapeutic product that —

- (a) is in liquid or solid form;

(b) contains codeine or its salts; and

(c) is intended for the treatment of coughs;

*[S 732/2021 wef 01/10/2021]*

“collaborative prescribing practitioner” has the meaning given by regulation 2 of the Healthcare Services (Collaborative Prescribing Service) Regulations 2023 (G.N. No. S 398/2023);

*[S 436/2023 wef 26/06/2023]*

“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 collaborative prescribing practitioner, or a person acting under the supervision of a qualified practitioner or collaborative prescribing practitioner; or

*[S 119/2018 wef 01/03/2018]*

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

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



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

*[Deleted by S 436/2023 wef 26/06/2023]*

*[Deleted by S 436/2023 wef 26/06/2023]*

“healthcare service licensee” means a person who holds a licence under the Healthcare Services Act 2020 to provide a licensable healthcare service;

*[S 436/2023 wef 26/06/2023]*

“importer’s licence” means an importer’s licence authorising the holder of the licence to import a therapeutic product under section 13 of the Act;

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

*[Deleted by S 436/2023 wef 26/06/2023]*

“licensable healthcare service” has the meaning given by section 3(1) of the Healthcare Services Act 2020;

*[S 436/2023 wef 26/06/2023]*

“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;

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*[Deleted by S 436/2023 wef 26/06/2023]*

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

“nursing home” means a nursing home within the meaning of the Private Hospitals and Medical Clinics Act 1980 that is licensed under that Act;

*[S 436/2023 wef 26/06/2023]*

“nursing home licensee” means a person who holds a licence under the Private Hospitals and Medical Clinics Act 1980 to operate a nursing home;

*[S 436/2023 wef 26/06/2023]*

“outpatient dental service licensee” means a healthcare service licensee who is authorised to provide an outpatient dental service;

*[S 436/2023 wef 26/06/2023]*

“outpatient medical service licensee” means a healthcare service licensee who is authorised to provide an outpatient medical service;

*[S 436/2023 wef 26/06/2023]*

“outpatient renal dialysis service licensee” means a healthcare service licensee who is authorised to provide an outpatient renal dialysis service;

*[S 436/2023 wef 26/06/2023]*

“personnel” means —

- (a) in relation to a healthcare service licensee providing a licensable healthcare service — any individual employed or engaged by the healthcare service licensee to assist the licensee in providing a licensable healthcare service; and
- (b) in relation to a nursing home licensee operating a nursing home — any individual employed or

engaged by the nursing home licensee to assist in the operation of the nursing home;

*[S 436/2023 wef 26/06/2023]*

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

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

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

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

*[Deleted by S 436/2023 wef 26/06/2023]*

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

“psychotropic substance” means a substance specified in the First Schedule;

“qualified pharmacist” means a person who —

(a) is registered as a pharmacist under the Pharmacists Registration Act 2007;

*[S 436/2023 wef 31/12/2021]*

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

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

“qualified practitioner” means —

- (a) a registered medical practitioner under the Medical Registration Act 1997; or

*[S 436/2023 wef 31/12/2021]*

- (b) a registered dentist under the Dental Registration Act 1999 whose name appears in the first division of the Register of Dentists maintained and kept under section 13(1)(a) of that Act;

*[S 436/2023 wef 31/12/2021]*

“relevant fee” means a fee specified in the Eighth Schedule to the Health Products (Fees) Regulations 2022 (G.N. No. S 450/2022);

*[S 458/2022 wef 01/07/2022]*

“remote service kiosk” has the meaning given by regulation 2(1) of the Healthcare Services (Outpatient Medical Service) Regulations 2023 (G.N. No. S 410/2023);

*[S 436/2023 wef 26/06/2023]*

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

- (a) placing it in a different container; or
- (b) changing the outer packaging or other packaging in which the container is further enclosed;

“specified healthcare service licensee” means a healthcare service licensee who is authorised to provide any of the following licensable healthcare services:

- (a) an acute hospital service;
- (b) an ambulatory surgical centre service;
- (c) an assisted reproduction service;

- (d) a blood banking service;
- (e) a community hospital service;
- (f) a contingency care service;
- (g) a nuclear medicine service;
- (h) an outpatient dental service;
- (i) an outpatient medical service;
- (j) an outpatient renal dialysis service;
- (k) a radiological service;

*[S 436/2023 wef 26/06/2023]*

“specified publication” means any of the following:

- (a) the British Pharmacopoeia;
- (b) the European Pharmacopoeia;
- (c) the United States Pharmacopoeia and the National Formulary;

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

“temporary premises” means any premises other than permanent premises;

*[S 436/2023 wef 26/06/2023]*

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

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

- (a) the quantity, liquid volume or weight of the therapeutic product;
- (b) the method of manufacture, production, or processing, of the therapeutic product;
- (c) the characteristics or composition of the therapeutic product;

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- (d) the fitness for purpose (including expiry date), dosage strength, or intended purpose, of the therapeutic product;
  - (e) any physical characteristics or presentation of the therapeutic product not referred to in paragraphs (a) to (d);
  - (f) the testing of the therapeutic product by any person and the results of the test;
  - (g) the approval of the therapeutic product by any person or its conformity with a product description approved by any person;
  - (h) the place or date of manufacture, production, or processing, of the therapeutic product;
  - (i) the name of the person who manufactured, produced or processed the therapeutic product;

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

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

- (a) is written and signed by a qualified practitioner or collaborative prescribing practitioner; and

*[S 119/2018 wef 01/03/2018]*

- (b) contains all of the following particulars:

- (i) the date of the prescription;
  - (ii) the name and address of the qualified practitioner or collaborative prescribing practitioner giving the prescription;

*[S 119/2018 wef 01/03/2018]*

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

- (iv) the name and total amount of the prescribed therapeutic product to be supplied to, and the dose to be taken by, the patient;
- (v) where the qualified practitioner or collaborative prescribing 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;  
*[S 119/2018 wef 01/03/2018]*
- (vi) where the prescription is given by a dentist, a declaration by the dentist that the prescription is “for dental treatment only”.

### **Scope of Regulations**

**3.** These Regulations do not apply to any therapeutic product that is clinical research material as defined in regulation 2(1) of the Health Products (Therapeutic Products as Clinical Research Materials) Regulations 2016 (G.N. No. S 332/2016).

## **PART 2**

### **MANUFACTURE AND IMPORT OF THERAPEUTIC PRODUCTS**

#### *Division 1 — Manufacture*

### **Requirements for issue of manufacturer’s licence**

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

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

- (b) the applicant is able to provide and maintain, or ensure the provision and maintenance of, such staff, premises, equipment and facilities for the handling and storage of the therapeutic product as are necessary to prevent the deterioration of the therapeutic product while it is in the applicant's ownership, possession or control;
- (c) the applicant is able to conduct all manufacturing operations in such a way as to ensure that the therapeutic product is of the correct identity and conforms with the applicable standards of strength, quality and purity for that therapeutic product; and
- (d) the applicant is able to comply with the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme Guide to Good Manufacturing Practice for Medicinal Products in relation to the manufacture of the therapeutic product.

### *Division 2 — Import*

#### **Requirements for issue of importer's licence**

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

- (a) the applicant is able to provide and maintain, or ensure the provision and maintenance of, such staff, premises, equipment and facilities for the handling and storage of the therapeutic product as are necessary to prevent the deterioration of the therapeutic product while it is in the applicant's ownership, possession or control;
- (b) the therapeutic product —
  - (i) is imported on behalf of a nursing home licensee or a specified healthcare service licensee pursuant to a valid prescription given by a qualified practitioner (who is a personnel of the nursing home licensee or



specified healthcare service licensee, as the case may be) for the use of the qualified practitioner's patient;  
*[S 436/2023 wef 26/06/2023]*

- (ii) is intended to be supplied solely for the purpose of scientific education or research and development, or for a non-clinical purpose;
  - (iii) is imported solely for the purpose of export;
  - (iv) is intended to be supplied for use on a ship, and the therapeutic product is one that is required to be carried on board the ship under the Merchant Shipping (Medical Stores) Regulations (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;  
*[S 436/2023 wef 31/12/2021]*
  - (v) is intended to be supplied for use on an aircraft, and the therapeutic product forms part of the medical supplies required under the Air Navigation Order (O 2) or any other written law, for the treatment of persons on board the aircraft;  
*[S 436/2023 wef 31/12/2021]*
  - (vi) is authorised for import by the registrant of the therapeutic product; or
  - (vii) is in all respects the same as a registered therapeutic product, the registrant of which has not authorised the applicant to import that registered therapeutic product; and
- (c) the applicant is able to comply with the requirements in the Authority's Guidance Notes on Good Distribution Practice for importers set out on the Authority's website if the therapeutic product is imported in accordance with sub-paragraph (b)(i), (vi) and (vii).

(2) In addition to the requirements in paragraph (1), an applicant who intends to import a therapeutic product under

paragraph (1)(b)(vii) must obtain the Authority's prior approval for each consignment of such therapeutic product to be imported.

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

### **Import of therapeutic products containing psychotropic substances**

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

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

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

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

## **PART 3**

### **SUPPLY OF THERAPEUTIC PRODUCTS**

#### **Requirements for purposes of section 17**

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

#### *Division 1 — Requirements for wholesale supply of therapeutic products*

### **Export of therapeutic products containing psychotropic substances**

8.—(1) Any person who intends to export a therapeutic product that contains a psychotropic substance must obtain the Authority's prior

approval for each consignment of such therapeutic product to be exported.

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

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

### **Export of codeine cough preparations**

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

*[S 732/2021 wef 01/10/2021]*

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

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

### **Wholesale of therapeutic products containing Second Schedule ingredients**

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

- (a) is a preparation containing an active ingredient specified in Part 1 of the Second Schedule;
- (b) is within any class of therapeutic products specified in Part 2 of that Schedule; or
- (c) is a preparation containing an active ingredient specified in Part 3 of that Schedule.

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

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

- (b) at the time of the supply, ensure that there is an order in writing, signed by the recipient, stating the recipient's name and address, trade, business or profession, and the name and total quantity of the therapeutic product supplied; and
  - (c) after the supply, insert in the appropriate entry in the record of supply prescribed by regulation 32(2)(b) a reference number by which the order can be identified.
- (3) Paragraph (2) does not apply to the supply by wholesale of a therapeutic product under regulation 47 or 59.

*Division 2 — Requirements for retail supply of registered therapeutic products*

**Supply by retail sale of prescription-only medicine**

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

- (a) the supply is made at or from a licensed retail pharmacy in accordance with regulation 3(1) and (2) of the Health Products (Licensing of Retail Pharmacies) Regulations 2016 (G.N. No. S 330/2016);
- (b) the supply is made by a nursing home licensee or a healthcare service licensee to a patient of the nursing home licensee or healthcare service licensee (as the case may be), and is in accordance with the written instructions of a qualified practitioner or collaborative prescribing practitioner who is a personnel of the nursing home licensee or healthcare service licensee, as the case may be;  
*[S 436/2023 wef 26/06/2023]*
- (c) the following requirements are satisfied:
  - (i) the person is a qualified practitioner or collaborative prescribing practitioner, or a person acting in accordance with the oral or written instructions of a qualified practitioner or collaborative prescribing practitioner;

- (ii) the supply is made to a patient under the care of the qualified practitioner or collaborative prescribing practitioner; or

*[S 119/2018 wef 01/03/2018]*

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

### **Supply by administration of prescription-only medicine**

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

- (a) the person is a qualified practitioner or collaborative prescribing practitioner, or a person acting in accordance with the oral or written instructions of a qualified practitioner or collaborative prescribing practitioner; or

*[S 119/2018 wef 01/03/2018]*

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

### **Supply by retail sale of pharmacy-only medicine**

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

- (a) the supply is made at or from a licensed retail pharmacy in accordance with regulation 3(1) of the Health Products (Licensing of Retail Pharmacies) Regulations 2016 (G.N. No. S 330/2016);
- (b) the supply is made by a nursing home licensee or a healthcare service licensee to a patient of the nursing home licensee or healthcare service licensee (as the case may be),

and is in accordance with the written instructions of a qualified practitioner or collaborative prescribing practitioner who is a personnel of the nursing home licensee or healthcare service licensee, as the case may be; or

*[S 436/2023 wef 26/06/2023]*

(c) the following requirements are satisfied:

- (i) the person is a qualified practitioner or collaborative prescribing practitioner, or a person acting in accordance with the oral or written instructions of a qualified practitioner or collaborative prescribing practitioner;
- (ii) the supply is made to a patient under the care of the qualified practitioner or collaborative prescribing practitioner.

*[S 119/2018 wef 01/03/2018]*

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

- (a) the date of the supply;
- (b) the name, identity card or other identification document number, and contact details, of the person to whom the pharmacy-only medicine is supplied;
- (c) the name, strength and total amount of pharmacy-only medicine to be supplied;
- (d) the dosage, and the frequency and purpose of the treatment for which the supply is made.

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

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

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

### **Restrictions on supply by retail sale of codeine cough preparations**

**14.—**(1) A qualified practitioner or qualified pharmacist who supplies by retail sale any codeine cough preparation must not supply more than the following to any individual within a period of 7 days:

- (a) where codeine cough preparations are supplied to the individual in liquid form only — an aggregate amount of 240 ml of codeine cough preparations;
- (b) where codeine cough preparations are supplied to the individual in solid form only or in both liquid and solid forms — an aggregate amount of 355 mg of codeine (calculated as codeine base) contained in the codeine cough preparations supplied.

(2) A qualified practitioner or qualified pharmacist who supplies by retail sale any codeine cough preparation must, on each occasion of the supply of the codeine cough preparation to an individual, provide professional counselling on the use of the codeine cough preparation.

(3) A qualified practitioner who supplies by retail sale any codeine cough preparation must, on each occasion of the supply of the codeine cough preparation to an individual, in addition to complying with regulation 16, record the purpose of the treatment for which the codeine cough preparation was supplied.

*[S 732/2021 wef 01/10/2021]*

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**Supply of general sale list medicine by retail sale vending machine**

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

- (a) the person's name and contact information is prominently displayed on the automatic vending machine;
- (b) the automatic vending machine is sufficiently equipped and secure to ensure appropriate storage conditions for the medicine;
- (c) the medicine is labelled and packaged in accordance with the conditions attached by the Authority to the registration of the medicine under the Act;
- (d) the package size of the medicine is the same as the package size specified for the registration of the medicine, and the total amount of the medicine in each package does not exceed a total dosage of 3 months per individual.

*Division 3 — Other requirements for supply of therapeutic products*

**Records of supply of prescribed therapeutic products**

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

*[S 119/2018 wef 01/03/2018]*

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

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



- (c) the name of the therapeutic product, being either the proprietary name or the appropriate non-proprietary name, and the total amount supplied;
- (d) if the therapeutic product is supplied by a qualified pharmacist or a person acting under the supervision of a qualified pharmacist, or at or from a licensed retail pharmacy, the name and address of the qualified practitioner or collaborative prescribing practitioner who signed the prescription.

*[S 119/2018 wef 01/03/2018]*

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

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

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

### **Supply by dispensing therapeutic products**

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

- (a) the name of the person to whom the therapeutic product is to be administered;
- (b) where the product is supplied or dispensed —
  - (i) at a nursing home or licensed retail pharmacy — the name, address and any identification number or logo of the nursing home or licensed retail pharmacy;
  - (ii) at any approved permanent premises by a healthcare service licensee under a business name — the business name, address of the approved permanent premises and any identification number or logo of the healthcare service licensee;

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- (iii) at any temporary premises or approved conveyance by a healthcare service licensee under a business name —
    - (A) if the healthcare service licensee is also approved under the Healthcare Services Act 2020 to provide the licensable healthcare service at any permanent premises under that business name — the business name, address of the approved permanent premises and any identification number or logo of the healthcare service licensee; or
    - (B) in any other case — the business name, address and any identification number or logo of the healthcare service licensee; or
  - (iv) by a healthcare service licensee using a remote service kiosk or by delivery under a business name —
    - (A) if the healthcare service licensee is also approved under the Healthcare Services Act 2020 to provide the licensable healthcare service at any permanent premises under that business name — the business name, address of the approved permanent premises and any identification number or logo of the healthcare service licensee; or
    - (B) in any other case — the business name, address and any identification number or logo of the healthcare service licensee;
- [S 436/2023 wef 26/06/2023]*
- (c) the date that the therapeutic product is dispensed;
  - (d) the directions for use of the therapeutic product;
  - (e) the name of the therapeutic product, being either the proprietary name or the appropriate non-proprietary name;

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

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

- (a) where the qualified practitioner or collaborative prescribing 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

*[S 119/2018 wef 01/03/2018]*

- (b) where the qualified practitioner or collaborative prescribing 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.

*[S 119/2018 wef 01/03/2018]*

(3) In this regulation, “relevant person” means —

- (a) a qualified practitioner or collaborative prescribing practitioner, or a person acting under the supervision of a qualified practitioner or collaborative prescribing practitioner; or

*[S 119/2018 wef 01/03/2018]*

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

*Division 4 — Requirements for wholesaler's licence*

**Requirements for issue of wholesaler's licence**

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

- (a) the applicant is able to provide and maintain, or ensure the provision and maintenance of, such staff, premises, equipment and facilities for the handling, storage and distribution of the therapeutic product as are necessary to prevent the deterioration of the therapeutic product while it is in the applicant's ownership, possession or control; and
- (b) the applicant is able to comply with the Authority's Guidance Notes on Good Distribution Practice for wholesalers set out on the Authority's website.

**PART 4**

**PRESENTATION OF THERAPEUTIC PRODUCTS**

**Trade descriptions**

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

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

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

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- (a) it contains any false statement or information concerning the therapeutic product; or
  - (b) it is likely to create an erroneous impression regarding the formulation, composition, quality, safety, efficacy or uses of the therapeutic product.
- (3) For the purposes of paragraph (1), a person applies a trade description to a therapeutic product if the person —
- (a) affixes or annexes the trade description to, or in any manner marks it on or incorporates it in —
    - (i) the therapeutic product; or
    - (ii) any thing in or on the therapeutic product or with which the therapeutic product is supplied;
  - (b) places the therapeutic product in, on or with any thing which the trade description has been affixed or annexed to, marked on or incorporated in; or
  - (c) makes any oral or written statement of the trade description, or uses the trade description in any other manner, which is likely to be understood as referring to the therapeutic product.
- (4) A person supplying a therapeutic product is taken to have applied a trade description to the therapeutic product if —
- (a) the therapeutic product is supplied pursuant to a request in which the trade description is used; and
  - (b) it is reasonable in the circumstances to infer that any therapeutic product so supplied will correspond to that trade description.

### **Information to be provided with therapeutic products**

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

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

- (b) the appropriate quantitative particulars of any active ingredient of the therapeutic product;
- (c) an appropriate control number, such as a serial number, batch number or lot number;
- (d) the expiry date of the therapeutic product;
- (e) where the therapeutic product is registered, the registration number assigned to the registered therapeutic product by the Authority.

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

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

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

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

- (a) must be provided in English; and
- (b) must be legible and indelible.

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

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

- (a) to stop disseminating, publishing or using the trade description with immediate effect;
- (b) to stop applying the trade description to the therapeutic product, or to stop supplying the therapeutic product applied with the trade description, with immediate effect;
- (c) to take such measures as may be reasonable and necessary in the circumstances to discontinue or remove any trade description that may already have been applied, disseminated, published or used;
- (d) to apply, disseminate or publish a corrective trade description in such manner and containing such information as the Authority may require.

(2) Where any manufacturer, importer, supplier or registrant of a therapeutic product fails to provide any information required by regulation 20 to accompany the supply of the therapeutic product, the Authority may order that manufacturer, importer, supplier or registrant, as the case may be, to take such corrective measures as the Authority may require, including —

- (a) to stop supplying the therapeutic product with immediate effect; or
- (b) to take such measures as may be reasonable and necessary in the circumstances to ensure that the therapeutic product is only supplied with the required information.

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

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

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

## PART 5

### REGISTRATION OF THERAPEUTIC PRODUCTS

#### **Requirements for registration**

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

- (a) that the overall intended benefits to a user of the therapeutic product outweigh the overall risks associated with the use of the therapeutic product; and
- (b) based on the formulation, manufacturing process controls, specifications and shelf life of the therapeutic product, and the stability of the therapeutic product under the recommended storage conditions, that the therapeutic product is suitable for its intended purpose and that any risk associated with its use is minimised.

#### **Whether therapeutic product subject to patent**

**23.—**(1) In dealing with an application for the registration of a therapeutic product, the Authority must consider whether a patent under the Patents Act 1994 is in force in respect of the therapeutic product and, if so —

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



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

- (i) the proprietor has consented to or has acquiesced in the grant of the registration of the therapeutic product to the applicant; or
- (ii) the patent is invalid or will not be infringed by the doing of the act for which the registration of the therapeutic product is sought.

*[S 436/2023 wef 31/12/2021]*

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

(a) whether a patent under the Patents Act 1994 is in force in respect of the therapeutic product; and

*[S 436/2023 wef 31/12/2021]*

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

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

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

(b) whether —

- (i) the proprietor has consented to or has acquiesced in the grant of the registration of the therapeutic product by the applicant; or
- (ii) in the opinion of the applicant and to the best of the applicant's belief, the patent is invalid or will not be infringed by the doing of the act for which the registration of the therapeutic product is sought; and

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

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

(5) Where the applicant is not the proprietor of a patent under the Patents Act 1994 that is in force in respect of the therapeutic product, the Authority may require the applicant to serve, in accordance with section 67 of the Act, on the proprietor of the patent, a notice in the form specified on the Authority's website, and within such time as the Authority may determine, if —

- (a) the applicant has declared that, in the applicant's opinion and to the best of the applicant's belief, the patent is invalid or will not be infringed by the doing of the act for which the registration is sought; or
- (b) the Authority considers it appropriate in any particular case for the applicant to do so.

*[S 436/2023 wef 31/12/2021]*

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

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

(8) If the Authority is satisfied that the notice mentioned in paragraph (5) has been served on the proprietor of the patent, the Authority may register the therapeutic product if the proprietor does not, before the 45th day after the date that notice is served on the proprietor —

- (a) apply to —
  - (i) a court for an order restraining the act for which the registration of the therapeutic product is sought; or
  - (ii) a court or the Registrar of Patents or a Deputy Registrar of Patents holding office under the Patents Act 1994, for a declaration that the patent is valid or

will be infringed by the doing of the act for which the registration of the therapeutic product is sought; and  
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- (b) give written notice to the Authority stating that such application in sub-paragraph (a) has been made, accompanied by evidence of the application.

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

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

### **Cancellation of registration of therapeutic product subject to patent dispute**

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

(a) that —

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

*[S 436/2023 wef 31/12/2021]*

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

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

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

### **Prescribed time for cancellation of registration of therapeutic product for non-payment of retention fee**

**24A.** For the purposes of section 37(2) of the Act, the prescribed time is 60 days after the anniversary of the date of the registration of the therapeutic product.

*[S 458/2022 wef 01/07/2022]*

### **Offences for making false patent declaration**

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

- (a) makes any statement or furnishes any document which the person knows or has reason to believe is false in a material particular; or
- (b) by the intentional suppression of any material fact, furnishes information which is misleading,

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

### **Protection of confidential supporting information relating to innovative therapeutic product applications**

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

- (a) must take reasonable steps to ensure that the confidential supporting information is kept confidential to the Authority; and
- (b) must not use that confidential supporting information for the purpose of determining whether to grant any other application to register a therapeutic product.

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

“confidential information” includes —

- (a) trade secrets; and
- (b) information that has commercial value that would be, or would be likely to be, diminished by disclosure;

“confidential supporting information” means confidential information given —

- (a) in, or in relation to, an innovative therapeutic product application; and
- (b) about the therapeutic product that is the subject of that application;

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

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

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

### **Circumstances where protection under regulation 26 does not apply**

**27.—**(1) Despite regulation 26, the Authority may, during the protected period in relation to confidential supporting information —

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- (a) disclose that confidential supporting information, or use that confidential supporting information for the purpose of determining whether to grant any other application to register a therapeutic product —
    - (i) with the consent of the applicant who made the application to which the confidential supporting information relates; or
    - (ii) if that disclosure or use is, in the opinion of the Authority, necessary to protect the health or safety of members of the public;
  - (b) disclose that confidential supporting information to a Government department or statutory body for the purpose of facilitating or assisting such Government department or statutory body in carrying out its duties if, in the opinion of the Authority, the Government department or statutory body, as the case may be, will take reasonable steps to ensure the confidential supporting information is kept confidential; or
  - (c) disclose that confidential supporting information to, if so requested by, any one or more of the following:
    - (i) the World Health Organization;
    - (ii) the Food and Agriculture Organization of the United Nations;
    - (iii) any regulatory agency of a country that is a party to the Agreement establishing the World Trade Organization adopted at Marrakesh on 15 April 1994;
    - (iv) any Advisory Committee established under section 10 of the Act.
- (2) The power to grant consent under paragraph (1)(a)(i) may be exercised by a person (*P*) other than the applicant mentioned in that paragraph if —

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- (a) that applicant —
    - (i) has notified the Authority in writing that *P* may grant that consent; and
    - (ii) has not notified the Authority in writing that *P*'s authority to grant that consent has been withdrawn; or
  - (b) that applicant's rights in respect of the relevant confidential supporting information have been transferred to *P* and the applicant or *P* has notified the Authority in writing of the transfer.

### **Disclosure of information on applications for registration**

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

- (a) any trade secret; and
- (b) any information that has commercial value that would be, or would be likely to be, diminished by the disclosure.

### **Registration exclusivity**

**29.** Where —

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

the Authority may not, for a period of 5 years after the date of the earlier registration, register, on the application of any other person, a similar therapeutic product on the basis of the earlier registration,

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unless the registrant of the earlier registration has consented to the registration on that basis.

## PART 6

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

#### *Division 1 — General duties*

#### **Duty to comply with enforcement requirements**

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

- (a) any premises that are used for the manufacture, supply or storage of therapeutic products; and
- (b) any conveyance that is being used for the transport of therapeutic products.

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

- (a) require any person having possession or control of any therapeutic product that is found during the inspection to furnish, without charge, a sample of such therapeutic product for the Authority's examination; and
- (b) take or cause to be taken any photograph of —
  - (i) the premises or conveyance mentioned in paragraph (1); or
  - (ii) any property or material found on the premises or in the conveyance.

#### **Duty to maintain records of manufacture**

**31.**—(1) A manufacturer of a therapeutic product, other than a nursing home licensee or a healthcare service 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).

*[S 436/2023 wef 26/06/2023]*

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

- (a) one year after the expiry date of the therapeutic product;
- (b) 5 years after the date of manufacture of the therapeutic product.

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

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

### **Duty to maintain records of receipt and supply**

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

- (a) a licensee or registrant of a therapeutic product; or
- (b) the supplier of a therapeutic product in accordance with regulation 47, 49, 51, 58(1)(a), (b), (c) or (d) or 60A(3) or (4).

*[S 969/2020 wef 01/12/2020]*

*[S 436/2023 wef 26/06/2023]*

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- (2) *P* must —
- (a) if *P* is not the manufacturer of the therapeutic product, maintain a record of every receipt by *P* of the therapeutic product;
  - (b) maintain a record of every supply by *P* of the therapeutic product; and
  - (c) produce for inspection by the Authority or an enforcement officer the record of every receipt or supply as and when required by the Authority or enforcement officer.
- (3) *P* must ensure that every record mentioned in paragraph (2) —
- (a) contains, in relation to each receipt by *P* of the therapeutic product, all of the following information:
    - (i) the proprietary name or appropriate non-proprietary name of the therapeutic product, if the therapeutic product is supplied by a manufacturer, importer or wholesaler, as the case may be;
    - (ii) the date on which the therapeutic product is received;
    - (iii) the name and address of the person from whom the therapeutic product is received;
    - (iv) the quantity of the therapeutic product received;
    - (v) the identification number (including the control number, lot number, batch number or serial number) of the therapeutic product received;
  - (b) contains, in relation to each supply by *P* of the therapeutic product, all of the following information:
    - (i) the proprietary name or appropriate non-proprietary name of the therapeutic product;
    - (ii) the date on which the therapeutic product is supplied;
    - (iii) the name and address of the person to whom the therapeutic product is supplied;
    - (iv) the quantity of the therapeutic product supplied;

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

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

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

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

### **Duty to maintain records of defects and adverse effects**

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

- (a) maintain a record of every event or other occurrence that reveals any defect in the therapeutic product or that concerns any adverse effect arising from the use of the therapeutic product; and
- (b) produce such record for inspection by the Authority or an enforcement officer as and when required by the Authority or enforcement officer.

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

- (a) contains all of the following information:
  - (i) the proprietary name or appropriate non-proprietary name of the therapeutic product which is defective or of which an adverse effect has arisen from its use;
  - (ii) the date on which the person first became aware of the event or occurrence;

- (iii) the identification number or mark (including the control number, lot number, batch number or serial number) of the therapeutic product;
  - (iv) the nature of the defect or adverse effect;
  - (v) any other information that the Authority may specify in writing; and
- (b) is retained for at least 2 years after the expiry date of the therapeutic product.

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

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

### **Duty to report defects and adverse effects**

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

- (a) if the defect represents a serious threat to persons or public health, within 48 hours; or
- (b) in all other cases, within 15 days,

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

(2) For the purposes of section 42(1)(b) of the Act, every manufacturer, importer, supplier or registrant of a therapeutic product must, upon becoming aware of any serious adverse reaction arising from the use of the therapeutic product, report the serious adverse reaction to the Authority immediately, but in any case

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no later than 15 days after the manufacturer, importer, supplier or registrant first becomes aware of the serious adverse reaction.

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

- (a) may result in a person’s death;
- (b) may threaten a person’s life;
- (c) results in a person being hospitalised or prolongs a person’s existing stay in hospital;
- (d) results in a person’s persistent or significant disability or incapacity;
- (e) results in a congenital anomaly or birth defect; or
- (f) is judged to be medically important even though the effect might not be immediately life-threatening or result in death or hospitalisation, but may jeopardise the person’s health or may require intervention to prevent the person’s death or one of the other outcomes mentioned in sub-paragraphs (c), (d) and (e).

### **Duty to notify Authority concerning recall**

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

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

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

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registrant of the therapeutic product to do either or both of the following:

- (a) investigate the matter occasioning the recall of the therapeutic product and provide a report of the findings of the investigation;
  - (b) take such other measures as the Authority thinks necessary.
- (4) A person to whom a notice in paragraph (3) is given must comply with the notice at the person's own cost and within the time specified in the notice or, if no time is specified in the notice, within a reasonable time after the date of the notice.
- (5) A person who fails to comply with paragraph (4) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$20,000 or to imprisonment for a term not exceeding 12 months or to both.

*Division 2 — Duties specific to licensees*

**Duty of licensed manufacturer**

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

- (a) must ensure, and maintain objective evidence to establish, that the manufacture of the therapeutic product complies with the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme Guide to Good Manufacturing Practice for Medicinal Products;
- (b) must provide and maintain, or ensure the provision and maintenance of, such staff, premises, equipment and facilities as are necessary for carrying out, in accordance with the holder's licence, such stages of the manufacture of the therapeutic product as are undertaken by the holder;
- (c) must not carry out any stages of manufacture of the therapeutic product in any premises not specified in the holder's licence;
- (d) must provide and maintain, or ensure the provision and maintenance of, such staff, premises, equipment and

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facilities for the handling and storage of the therapeutic product as are necessary to prevent the deterioration of the therapeutic product while it is in the holder's ownership, possession or control;

- (e) must only use the premises specified in the holder's licence, or such other premises as may be approved from time to time by the Authority, for handling or storing the therapeutic product;
- (f) must carry out, or arrange for a testing laboratory as specified in the licence to carry out, tests on the strength, quality and purity of the therapeutic product to ensure that the standards of the therapeutic product comply with any applicable standard set by the Authority for the therapeutic product;
- (g) must conduct all manufacturing operations in such a way as to ensure that the therapeutic product is of the correct identity and conforms with the applicable standards of strength, quality and purity; and
- (h) must ensure that any tests for determining conformity with the applicable standards and specifications applying to the therapeutic product are, unless otherwise provided in the licence, applied to samples taken after all manufacturing processes have been completed, or at such earlier stage in the manufacture as may be approved by the Authority.

### **Duty of licensed importer**

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

- (a) must ensure, and maintain objective evidence to establish, that the handling and storage of the therapeutic product complies with any standard set out by the Authority on the Authority's website for the therapeutic product;
- (b) must provide and maintain, or ensure the provision and maintenance of, such staff, premises, equipment and facilities for the handling and storage of the therapeutic

product as are necessary to prevent the deterioration of the therapeutic product while it is in the holder's ownership, possession or control; and

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

### **Duty of licensed wholesaler**

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

- (a) must ensure, and maintain objective evidence to establish, that the handling, storage and distribution of the therapeutic product complies with any standard set out by the Authority on the Authority's website for the therapeutic product;
- (b) may only supply the therapeutic product by wholesale to a person who may lawfully supply such therapeutic products in accordance with the Act;
- (c) must provide and maintain, or ensure the provision and maintenance of, such staff, premises, equipment and facilities for the handling, storage and distribution of the therapeutic product as are necessary to prevent the deterioration of the therapeutic product while it is in the holder's ownership, possession or control; and
- (d) must not use, for any purpose mentioned in paragraph (c), any premises other than the premises specified in the holder's licence, or such other premises as may be approved from time to time by the Authority.

### **Responsible person**

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



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(2) The licensee must ensure that —

- (a) the responsible person has adequate knowledge of the activities to be carried out and of the procedures to be performed under the licence;
- (b) the responsible person has relevant working experience relating to those activities and procedures;
- (c) in the case of a manufacturer's licence, the responsible person named in the licence has practical experience in production supervision or in testing and checking to ensure the quality of therapeutic products or related health products;
- (d) in the case of an importer's licence or wholesaler's licence for the import or supply of any therapeutic product that is not registered at the request of a qualified practitioner for the use of the qualified practitioner's patient, the responsible person named in the licence is a qualified pharmacist or such other person as the Authority may approve;
- (e) in the case of an importer's licence or a wholesaler's licence for the import or supply by wholesale of prescription-only medicine or pharmacy-only medicine, the responsible person named in the licence is a qualified pharmacist or such other person as the Authority may approve; and
- (f) at any time, there is at least one responsible person who is contactable by the Authority by way of a mobile telephone number or an email address.

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

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

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**Offence for contravention of duties**

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

**Changes affecting licence**

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

- (a) any change or proposed change to any particulars furnished by the licensee to the Authority in relation to the application for the licensee's licence; and
- (b) any change or proposed change that significantly affects the activities of the licensee that are authorised by that licence.

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

- (a) be made in such form and manner as the Authority may require;
- (b) be submitted within such time as the Authority may specify in the conditions of the licence;
- (c) be accompanied by such particulars, information, documents and samples as the Authority may require;
- (d) be accompanied by the relevant fee; and

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

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

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

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

- (a) the premises where the licensee operates;
- (b) the facilities and equipment used by the licensee;
- (c) the operations and processes carried out by the licensee;
- (d) the responsible person mentioned in regulation 39.

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

(7) A licensee who —

- (a) in compliance or purported compliance with paragraph (1), furnishes the Authority with any notice under paragraph (1) which the licensee knows is false or misleading; or
- (b) fails to comply with paragraph (3),

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

### *Division 3 — Duties specific to registrants*

#### **Changes concerning registered therapeutic product**

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

- (a) any change to any particulars provided in relation to the registration of the therapeutic product; or
- (b) any change that may affect the quality, safety or efficacy of the therapeutic product.

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

- (a) be made in such form and manner as the Authority may require;
- (b) be submitted within such time as the Authority may specify in the conditions of the registration of the therapeutic product;
- (c) be accompanied by such particulars, information, documents and samples as the Authority may require;
- (d) be accompanied by the relevant fee; and  
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- (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.

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**Information on validity of data submitted to or considered by Authority**

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

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

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

**Submission of benefit-risk evaluation reports**

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

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

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

(b) annually, for the next 3 years.

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

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

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

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

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

### **Duty to carry out risk management plan**

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

- (a) producing and distributing educational material;
- (b) producing and distributing safety information;
- (c) performing clinical studies of the therapeutic product;
- (d) implementing active surveillance programmes of the therapeutic product;
- (e) implementing programmes to restrict the supply of the therapeutic product.

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

## **PART 7**

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

#### *Division 1 — Nursing homes licensees and specified healthcare service licensees*

*[S 436/2023 wef 26/06/2023]*

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**Compounding of therapeutic products at nursing homes, or approved permanent premises, etc., of specified healthcare service licensees without manufacturer's licence**

**46.—**(1) A nursing home licensee or a specified healthcare service licensee 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) where the therapeutic product is compounded by a nursing home licensee —
    - (A) at the nursing home of the nursing home licensee or, in the case of a sterile therapeutic product, at a practice setting within the nursing home where standards established for the operation of clean rooms and the preparation of sterile products are in place and properly documented; and
    - (B) by or under the supervision of a qualified practitioner or a qualified pharmacist who is a personnel of the nursing home licensee; or
  - (ii) where the therapeutic product is compounded by a specified healthcare service licensee —
    - (A) at any approved permanent premises, temporary premises or approved conveyance of the specified healthcare service licensee or, in the case of a sterile therapeutic product, at a practice setting within the approved permanent premises, temporary premises or approved conveyance where standards established for the operation of clean rooms and the

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preparation of sterile products are in place and properly documented; and

- (B) by or under the supervision of a qualified practitioner or a qualified pharmacist who is a personnel of the specified healthcare service licensee; and

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- (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.

*[S 436/2023 wef 26/06/2023]*

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

- (a) the therapeutic product is for the use of any patient under the care of the qualified practitioner; and
- (b) the therapeutic product contains an active ingredient specified in Part 1 of the Second Schedule or is within any class of therapeutic products specified in Part 2 of that Schedule.

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

(4) It does not matter whether the patient mentioned in paragraph (2) is or is not a patient —

- (a) at the nursing home at which the compounding is carried out; or
- (b) at the approved permanent premises, temporary premises or approved conveyance of the specified healthcare service licensee at which the compounding is carried out.

*[S 436/2023 wef 26/06/2023]*

(5) A therapeutic product compounded under paragraph (1) by a specified healthcare service licensee who is authorised to provide an outpatient dental service, outpatient medical service or outpatient renal dialysis service at any approved permanent premises, temporary



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premises or approved conveyance, must not be supplied to any of the following unless the approval of the Authority has been obtained for the supply:

- (a) a nursing home;
- (b) any approved permanent premises of the specified healthcare service licensee (other than the approved permanent premises at which the therapeutic product was compounded);
- (c) any approved permanent premises of another specified healthcare service licensee.

*[S 436/2023 wef 26/06/2023]*

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

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

*[S 436/2023 wef 26/06/2023]*

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

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

*[S 436/2023 wef 26/06/2023]*

### **Transfer of therapeutic products by nursing homes licensees and specified healthcare service licensees without wholesaler's licence**

**47.—**(1) A nursing home licensee may, in the case of a therapeutic product compounded by the nursing home licensee under

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regulation 46(1) at a nursing home, transfer the nursing home licensee's stock of the therapeutic product at the nursing home to any of the following without holding a wholesaler's licence:

- (a) another nursing home of the nursing home licensee;
- (b) a nursing home of another nursing home licensee;
- (c) any approved permanent premises, temporary premises or approved conveyance of a specified healthcare service licensee.

(2) A specified healthcare service licensee (other than an outpatient dental service licensee, outpatient medical service licensee or outpatient renal dialysis licensee) (called in this paragraph *A*) may, in the case of a therapeutic product compounded by *A* under regulation 46(1) at any approved permanent premises, temporary premises or approved conveyance, transfer *A*'s stock of the therapeutic product at the approved permanent premises, temporary premises or approved conveyance (as the case may be) to any of the following without holding a wholesaler's licence:

- (a) a nursing home;
- (b) another approved permanent premises, temporary premises or approved conveyance of *A*;
- (c) any approved permanent premises, temporary premises or approved conveyance of another specified healthcare service licensee.

(3) A specified healthcare service licensee who is an outpatient dental service licensee, outpatient medical service licensee or outpatient renal dialysis service licensee (called in this paragraph *B*) may, in the case of a therapeutic product compounded by *B* under regulation 46(1) at any approved permanent premises, temporary premises or approved conveyance, transfer *B*'s stock of the therapeutic product at the approved permanent premises, temporary premises or approved conveyance (as the case may be) to any of the following without holding a wholesaler's licence, if the approval of the Authority has been obtained under regulation 46(5) for the transfer:

- (a) a nursing home;
- (b) any approved permanent premises of B;
- (c) any approved permanent premises of another specified healthcare service licensee.

(4) A nursing home licensee or a specified healthcare service licensee (called in this paragraph *C*) may, in the case of a therapeutic product that is imported by *C* under regulation 51 or imported by a licensed importer under regulation 58(1)(f), transfer *C*'s stock of the therapeutic product to another nursing home licensee or specified healthcare service licensee without holding a wholesaler's licence.

*[S 436/2023 wef 26/06/2023]*

### *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

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sterile products are in place and properly documented; and

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

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

- (a) a valid prescription given by the qualified practitioner; or  
(b) the written instructions of the qualified practitioner, if the qualified practitioner is a personnel of a nursing home licensee or a specified healthcare service licensee.

*[S 436/2023 wef 26/06/2023]*

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

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

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

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

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

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

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

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

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

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

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

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

- (a) is to a nursing home licensee or a healthcare service licensee;

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- (b) is for use on a ship or an aircraft in accordance with the requirements in regulation 5(1)(b)(iv) or (v), respectively;
- (c) is for the purpose of scientific education or research and development, or for a non-clinical purpose;
- (d) is to a Government department or statutory board for the provision of public services;

- (e) is between licensed retail pharmacy outlets under the same management chain; or
- (f) consists of the supply of registered therapeutic products to companies outside Singapore for the purpose of any business or trade carried out by those companies.

*Division 3 — Named patients*

**Re-labelling of therapeutic products without manufacturer's licence**

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

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

**51.—**(1) Subject to paragraph (3), a nursing home licensee or a specified healthcare service licensee may, without holding an importer's licence, import a therapeutic product that is not registered, if the therapeutic product —

- (a) is required by, and on the written instructions of, a qualified practitioner who is a personnel of the nursing home licensee or specified healthcare service licensee; and
- (b) is for the use of the qualified practitioner's patient.

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

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

- (a) a total dosage of 3 months per patient as recommended by the manufacturer of the therapeutic product; or
  - (b) such other quantity as approved by the Authority.
- (4) An application for the Authority's approval under paragraph (3) must be made in the form and manner specified on the Authority's website.

#### *Division 4 — Personal imports*

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

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

- (a) any psychotropic substance; or
  - (b) an amount greater than the amount specified in the second column of the Seventh Schedule of any substance specified in the first column of that Schedule.
- (2) The amount of the therapeutic product imported under paragraph (1) must not exceed a total dosage of 3 months per individual as recommended by —
- (a) the manufacturer of the therapeutic product; or
  - (b) a foreign doctor or dentist by way of a written recommendation, or a qualified practitioner by way of a valid prescription.

#### *Division 5 — Wholesale of therapeutic products for export*

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

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

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

*Division 6 — Other exceptions*

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

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

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

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

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

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

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



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**Therapeutic products for research or non-clinical purposes**

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

(a) is solely for —

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

(ii) a non-clinical purpose; and

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

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

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

## PART 8

### EXCEPTIONS — SUPPLY OF THERAPEUTIC PRODUCTS WITHOUT REGISTRATION

#### **Prescribed exceptions**

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

(a) the supply of a therapeutic product compounded under regulation 46 by a nursing home licensee at a nursing home of the nursing home to any of the following:

(i) another nursing home of the nursing home licensee;

(ii) a nursing home of another nursing home licensee;

(iii) any approved permanent premises, temporary premises or approved conveyance of a specified healthcare service licensee (other than an outpatient

dental service licensee, outpatient medical service licensee or outpatient renal dialysis service licensee);

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(b) the supply of a therapeutic product compounded under regulation 46 by a specified healthcare service licensee (other than an outpatient dental service licensee, outpatient medical service licensee or outpatient renal dialysis service licensee) at any approved permanent premises, temporary premises or approved conveyance of the specified healthcare service licensee to any of the following:

(i) a nursing home;

(ii) another approved permanent premises, temporary premises or approved conveyance of that specified healthcare service licensee;

(iii) any approved permanent premises, temporary premises or approved conveyance of another specified healthcare service licensee (other than an outpatient dental service licensee, outpatient medical service licensee or outpatient renal dialysis service licensee);

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(c) the supply of a therapeutic product compounded under regulation 46 by a nursing home licensee or a specified healthcare service licensee (other than an outpatient dental service licensee, outpatient medical service licensee or outpatient renal dialysis service licensee) to a patient of a qualified practitioner, who is a personnel of any nursing home licensee or specified healthcare service licensee, as the case may be;

*[S 436/2023 wef 26/06/2023]*

(ca) the supply of a therapeutic product compounded under regulation 46 by a specified healthcare service licensee who is an outpatient dental service licensee, outpatient medical service licensee or outpatient renal dialysis service licensee at any approved permanent premises, temporary premises or approved conveyance, for the use of a patient of a qualified practitioner and, if the supply for this purpose

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involves the supply by the specified healthcare service licensee to —

- (i) a nursing home;
- (ii) another approved permanent premises of the specified healthcare service licensee; or
- (iii) any approved permanent premises of another specified healthcare service licensee,

the Authority's approval for the supply has been obtained under regulation 46(5);

*[S 436/2023 wef 26/06/2023]*

- (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 nursing home licensee or a specified healthcare service licensee in accordance with the requirements in regulation 5(1)(b)(i);

*[S 436/2023 wef 26/06/2023]*

- (g) the supply by a nursing home licensee or a specified healthcare service licensee of a therapeutic product that is imported under regulation 51(1) to a patient of a qualified practitioner, who is a personnel of the nursing home licensee or specified healthcare service licensee;

*[S 436/2023 wef 26/06/2023]*

- (h) the supply of a therapeutic product by a holder of a pharmacy licence pursuant to a valid prescription given by a qualified practitioner for the use of the qualified practitioner's patient under regulation 51(2);
- (i) the supply of a therapeutic product by a person, who has imported the therapeutic product under regulation 52, to a member of the person's family;

- (j) the supply of a therapeutic product for use on a ship or an aircraft in accordance with the requirements in regulation 5(1)(b)(iv) or (v), respectively;
- (k) the supply of a therapeutic product for —
  - (i) the purpose of scientific education or research and development; or
  - (ii) a non-clinical purpose,provided there is no supply of the therapeutic product to the public;
- (l) the supply by wholesale of a therapeutic product that does not contain a psychotropic substance or is not a controlled drug and is —
  - (i) manufactured solely for export; or
  - (ii) imported solely for re-export;
- (m) the export of any therapeutic product, subject to the approval of the Authority under regulation 8 or 9, where applicable.

(2) In paragraph (1)(l), “controlled drug” has the same meaning as in the Misuse of Drugs Act 1973.

*[S 436/2023 wef 31/12/2021]*

### **Supply of therapeutic products compounded under contractual agreement with licensed manufacturer**

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

- (a) by a licensed manufacturer of the therapeutic product to —
  - (i) a nursing home licensee for the use of a patient of the nursing home licensee; or
  - (ii) a specified healthcare service licensee for the use of a patient of the specified healthcare service licensee;

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- (b) by a nursing home licensee to a patient of the nursing home licensee;
  - (c) by a specified healthcare service licensee to a patient of the specified healthcare service licensee.
- (2) For the purposes of paragraph (1), the therapeutic product must be compounded —
- (a) under an agreement between the licensed manufacturer of the therapeutic product and the nursing home licensee mentioned in paragraph (1)(a)(i) or (b), or the specified healthcare service licensee mentioned in paragraph (1)(a)(ii) or (c);
  - (b) in accordance with the chemical composition and the written instructions of a qualified practitioner who is a personnel of —
    - (i) the nursing home licensee mentioned in paragraph (1)(a)(i) or (b) (as the case may be) for the use solely by or in connection with the patient mentioned in that paragraph; or
    - (ii) the specified healthcare service licensee mentioned in paragraph (1)(a)(ii) or (c) (as the case may be) for the use solely by or in connection with the patient mentioned in that paragraph;
  - (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 of the therapeutic product.
- (3) Paragraph (2)(b) does not apply to prohibit the supply of a therapeutic product that is not registered to any patient of a nursing home licensee mentioned in paragraph (1)(a)(i) or (b) or a specified healthcare service licensee mentioned in paragraph (1)(a)(ii) or (c), if the requirements mentioned in paragraph (2)(a), (c) and (d) are satisfied and the compounding consists only of repackaging for the purpose of dispensing the therapeutic product.

*[S 436/2023 wef 26/06/2023]*

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**Previously registered therapeutic products**

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

- (a) the cancellation of the registration is either made by the Authority under section 37(2) of the Act or upon the application of the registrant under section 37(3) of the Act;
- (b) the supplier has taken possession of the therapeutic product before the cancellation of its registration; and
- (c) the Authority does not direct a recall of the therapeutic product from the market.

**PART 8A****EXCEPTION — EMERGENCY THERAPEUTIC PRODUCTS**

*[S 969/2020 wef 01/12/2020]*

**Manufacture, import and supply of emergency therapeutic product**

**60A.**—(1) For the purposes of section 12(1) of the Act and without prejudice to regulations 30, 31, 33, 34 and 35, the manufacture of an emergency therapeutic product for or on behalf of the Government is a prescribed exception to the prohibition in that provision against the manufacture of a therapeutic product without a licence.

(2) For the purposes of section 13(1) of the Act and without prejudice to regulations 30, 33, 34 and 35, the import of an emergency therapeutic product for or on behalf of the Government is a prescribed exception to the prohibition in that provision against the import of a therapeutic product without a licence.

(3) For the purposes of section 14(1) of the Act and without prejudice to regulations 30, 32, 34 and 35, the supply by wholesale of an emergency therapeutic product for or on behalf of the Government

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is a prescribed exception to the prohibition in that provision against the supply by wholesale of a therapeutic product without a licence.

(4) For the purposes of section 15(1) of the Act and without prejudice to regulations 30, 32, 34 and 35, the supply of an emergency therapeutic product for or on behalf of the Government is a prescribed exception to the prohibition in that provision against the supply of a therapeutic product that is not registered.

(5) In this regulation —

“civil defence emergency” means a civil defence emergency declared under section 102(1) of the Civil Defence Act 1986;

*[S 436/2023 wef 31/12/2021]*

“emergency therapeutic product” means a therapeutic product that is for such time designated by the Minister as an emergency therapeutic product for the purposes of this regulation, where —

(a) the therapeutic product is needed —

- (i) to treat any medical condition resulting from a civil defence emergency;
- (ii) to prevent the spread or possible outbreak of an infectious disease; or
- (iii) to treat an infectious disease or any medical condition associated with an infectious disease, where the medical condition or infectious disease is potentially serious or life-threatening; and

(b) in the opinion of the Authority, there is —

- (i) preliminary scientific evidence that the therapeutic product has the potential —
  - (A) to treat the medical condition resulting from the civil defence emergency;
  - (B) to prevent the spread or possible outbreak of the infectious disease; or

(C) to treat the infectious disease or any medical condition associated with the infectious disease,

as the case may be; and

(ii) ongoing scientific evidence that the potential benefits of the therapeutic product outweigh the known risks of the therapeutic product, to a person on whom the therapeutic product is used;

“infectious disease” has the meaning given by section 2 of the Infectious Diseases Act 1976.

*[S 436/2023 wef 31/12/2021]*

*[S 969/2020 wef 01/12/2020]*

## 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.

*[S 458/2022 wef 01/07/2022]*



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**Certificate of manufacturing standard of therapeutic products**

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

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

(3) An application for a GMP Certificate must —

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

(b) be accompanied by the relevant fee.

*[S 458/2022 wef 01/07/2022]*

(4) In this regulation —

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

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

*[S 458/2022 wef 01/07/2022]*

**Certificate of distribution standard of therapeutic products**

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

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

(3) An application for a GDP Certificate must —

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

(b) be accompanied by the relevant fee.

*[S 458/2022 wef 01/07/2022]*

(4) In this regulation —

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

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

*[S 458/2022 wef 01/07/2022]*

### **Other certificates or documents**

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

*[S 458/2022 wef 01/07/2022]*

### **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

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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.

**68.** *[Deleted by S 458/2022 wef 01/07/2022]*

## **FIRST SCHEDULE**

Regulation 2(1)

### **PSYCHOTROPIC SUBSTANCES**

1. The following substances:

Allobarbitol

Alprazolam

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

Aminorex

Amobarbital

Barbital

Bromazepam

FIRST SCHEDULE — *continued*

Brotizolam  
Butalbital  
Butobarbital  
Camazepam  
Cathine  
Chlordiazepoxide  
Clobazam  
Clonazepam  
Clorazepate  
Clotiazepam  
Cloxazolam  
Cyclobarbital  
Delorazepam  
Diazepam  
Estazolam  
Ethchlorvynol  
Ethinamate  
Ethyl loflazepate  
Etilamfetamine  
Fencamfamin  
Fenproporex  
Fludiazepam  
Flurazepam  
Glutethimide  
Halazepam  
Haloxazolam  
Ketazolam  
Lefetamine  
Loprazolam

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FIRST SCHEDULE — *continued*

Lorazepam  
Lormetazepam  
Mazindol  
Medazepam  
Mefenorex  
Meprobamate  
Mesocarb  
Methylphenobarbital  
Methypylon  
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.

FIRST SCHEDULE — *continued*

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

## SECOND SCHEDULE

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

## PART 1

## ACTIVE INGREDIENTS IN PRESCRIPTION-ONLY MEDICINES

(±)-4-ethyl-2, 5-dimethoxy- $\alpha$ -phenethylamine (2C-E)

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

2-Phenylcinchoninic acid; 2-salicylcinchoninic acid

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

5-Phenylhydantoin

Abacavir

Abatacept

Abciximab

Abiraterone

Acamprosate

Acarbose

Acebutolol

Aceclofenac

Acemetacin

Acepromazine

Acetanilide; alkyl acetanilides

Acetazolamide

Acetohexamide

Acetorphine

Acetylcarbromal

Acetylcysteine

Acetyldigoxin

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SECOND SCHEDULE — *continued*

Acetyldihydrocodeine  
Acetylmethadol  
Acetylstrophanthidin  
Acipimox  
Acitretin  
Acrivastine  
Actinomycins  
Acyclovir  
Adalimumab  
Adapalene  
Adefovir  
Adicillin  
Adiphenine  
Adrenaline  
Adrenocorticotrophic hormone (ACTH)  
Afatinib  
Aflibercept  
Agalsidase beta  
Agomelatine  
Alatrofloxacin  
Alcaftadine  
Alclofenac  
Alclometasone  
Alcuronium  
Aldesleukin  
Aldosterone  
Alefacept  
Alemtuzumab  
Alendronic acid

SECOND SCHEDULE — *continued*

Alfacalcidol  
Alfentanil  
Alfuzosin  
Algestone  
Alglucosidase alfa  
Aliskiren  
Allobarbitone  
Allopurinol  
Allylisopropylacetylurea  
Allyloestrenol  
Allylprodine  
Alminoprofen  
Almitrine  
Alogliptin  
Alosetron  
Alphacalcidol  
Alphacetylmethadol  
Alphachloralose  
Alphadolone  
Alphameprodine  
Alphamethadol  
Alphaprodine  
Alphaxalone  
Alprazolam  
Alprenolol  
Alprostadil  
Alseroxylon  
Alteplase  
Altretamine



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SECOND SCHEDULE — *continued*

Amantadine

Ambenonium

Ambroxol

Ambuside

Ambutonium

Ametazole

Amethocaine

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

Amidopyrine

Amifostine

Amikacin

Amiloride

Amineptine

Aminocaproic acid

Aminoglutethimide

Aminophylline

Aminopterin

Aminorex

Amiodarone

Amisulpride

Amitriptyline

Amlodipine

Ammonium lactate

Amoxycillin

Amphetamine

Amphotycin

Amphotericin B

Ampicillin

Amprenavir

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SECOND SCHEDULE — *continued*

Amrinone  
Amsacrine (M-AMSA)  
Amylobarbitone  
Amylocaine  
Anagrelide  
Anastrozole  
Ancrod  
Androsterone  
Angiotensin amide  
Anidulafungin  
Anileridine  
Anistreplase  
Antazoline  
Apixaban  
Apomorphine  
Apraclonidine  
Apramycin  
Aprepitant  
Aprobarbitone  
Aprotinin  
Aripiprazole  
Arotinolol  
Arsphenamine  
Arteether  
Artemether  
Artemisinin  
Artesunate  
Articaine  
Asenapine

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SECOND SCHEDULE — *continued*

Aspoxicillin  
Astemizole  
Asunaprevir  
Atazanavir  
Atenolol  
Atomoxetine  
Atorvastatin  
Atosiban  
Atovaquone  
Atracurium  
Atropine  
Auranofin  
Axitinib  
Azacitidine  
Azacyclonol  
Azaperone  
Azapropazone  
Azasetron  
Azatadine  
Azathioprine  
Azelaic acid  
Azelastine  
Azidamphenicol  
Azidocillin  
Azilsartan  
Azithromycin  
Aztreonam  
Bacampicillin  
Bacitracin

SECOND SCHEDULE — *continued*

Baclofen  
Bambermycin  
Bamipine  
Barbitone  
Barbituric acid  
Basiliximab  
Becaplermin  
Beclamide  
Beclomethasone  
Befunolol  
Bekanamycin  
Belimumab  
Bemegride  
Benactyzine; its quarternary compounds  
Benapryzine  
Benazepril  
Bendamustine hydrochloride  
Bendrofluazide  
Benethamine penicillin  
Benfluorex  
Benoxaprofen  
Benperidol  
Benserazide  
Benzamidosalicylic acid  
Benzathine penicillin  
Benzbromarone  
Benzethidine  
Benzhexol  
Benzilonium

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SECOND SCHEDULE — *continued*

Benzocaine  
Benzoctamine  
Benzoestrol  
Benzphetamine  
Benzquinamide  
Benzthiazide  
Benztropine and its homologues  
Benzylfentanyl  
Benzylmorphine  
Benzylpenicillin  
Besifloxacin  
Betahistine  
Betameprodine  
Betamethadol  
Betamethasone  
Betaprodine  
Betaxolol  
Bethanechol  
Bethanidine  
Betiatide  
Bevacizumab  
Bevonium methyl sulphate  
Bezafibrate  
Bezitramide  
Bicalutamide  
Bicisate dihydrochloride  
Bifonazole  
Bilastine  
Bimatoprost

SECOND SCHEDULE — *continued*

Biperiden  
Bisoprolol  
Bleomycin  
Boceprevir  
Boldenone undecenoate  
Bopindolol  
Bortezomib  
Bosentan  
Botulinum toxin  
Brentuximab  
Bretylum  
Brimonidine  
Brinzolamide  
Brolamfetamine  
Bromazepam  
Bromhexine  
Bromocriptine  
Bromodiphenhydramine  
Bromvaletone  
Brotizolam  
Budesonide  
Bufexamac  
Buflomedil  
Buformin  
Bumadizone calcium  
Bumetanide  
Bunazosin  
Buphenine hydrochloride  
Bupivacaine

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SECOND SCHEDULE — *continued*

Bupranolol  
Buprenorphine  
Bupropion  
Buserelin  
Buspirone  
Busulphan  
Butacaine  
Butalbital  
Butamirate  
Butanilicaine  
Butizide  
Butobarbitone  
Butoconazole  
Butriptyline  
Butropium bromide  
Butylchloral hydrate  
Cabazitaxel  
Cabergoline  
Cabimicina  
Calcipotriol  
Calcitonin  
Calcitriol  
Calcium barbiturate  
Calcium carbimide  
Calcium dobesilate  
Calfactant  
Camazepam  
Canagliflozin  
Canakinumab

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SECOND SCHEDULE — *continued*

Candesartan  
Candicidin  
Capecitabine  
Capreomycin  
Captodiamine  
Captopril  
Caramiphen  
Carbachol  
Carbamazepine  
Carbenicillin  
Carbenoxolone  
Carbetocin  
Carbidopa  
Carbimazole  
Carboplatin  
Carboprost  
Carbromal  
Carbutamide  
Carfecillin  
Carfentanil  
Carisoprodol  
Carmustine  
Carperidine  
Carprofen  
Carteolol  
Carvedilol  
Caspofungin  
Cathine  
Cathinone



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SECOND SCHEDULE — *continued*

Cefaclor  
Cefadroxil  
Cefamandole  
Cefatrizine  
Cefdinir  
Cefepime  
Cefixime  
Cefodizime  
Cefoperazone  
Cefotaxime  
Cefotiam  
Cefoxitin  
Cefpirome  
Cefprozil  
Cefsulodin  
Ceftaroline  
Ceftazidime  
Ceftibuten  
Ceftizoxime  
Ceftriaxone  
Cefuroxime  
Celecoxib  
Cephalexin  
Cephaloglycin  
Cephaloram  
Cephaloridine  
Cephalothin  
Cephazolin  
Cephradine

SECOND SCHEDULE — *continued*

Ceritinib  
Cerivastatin  
Certolizumab  
Cetrorelix  
Cetuximab  
Chenodeoxycholic acid  
Chloral hydrate  
Chlorambucil  
Chloramphenicol  
Chlorcyclizine  
Chlordiazepoxide  
Chlormadinone  
Chlormerodrin  
Chlormethiazole  
Chlormezanone  
Chlormidazole  
Chlorothiazide  
Chloroquine  
Chlorpheniramine  
Chlorphenoxamine  
Chlorphentermine  
Chlorpromazine  
Chlorpropamide  
Chlorprothixene and other derivatives of 9-methylenethiazanthene  
Chlorquinaldol  
Chlortetracycline  
Chlorthalidone and other derivatives of o-chlorobenzene sulphonamide  
Chlorzoxazone  
Cholestyramine

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SECOND SCHEDULE — *continued*

Choline Theophyllinate  
Chorionic gonadotrophin  
Chromium [51CR] Edetate  
Chromomycin A  
Ciclacillin  
Ciclesonide  
Ciclopirox  
Cilastatin  
Cilazapril  
Cilostazol  
Cimetidine  
Cinacalcet  
Cinchocaine  
Ciprofibrate  
Ciprofloxacin  
Cisapride  
Cisatracurium  
Cisplatin  
Citalopram  
Citicoline  
Cladribine  
Clarithromycin  
Clavulanic acid  
Clebopride  
Clemastine  
Clemizole  
Clenbuterol  
Clidinium  
Clindamycin

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SECOND SCHEDULE — *continued*

Clioquinol  
Clobazam  
Clobenzorex  
Clobetasol  
Clobetasone  
Clobutinol  
Clodronic acid  
Clofarabine  
Clofazimine  
Clofedanol  
Clofibrate  
Clomiphene  
Clomipramine  
Clomocycline  
Clonazepam  
Clonidine  
Clonitazene  
Clopamide  
Clopenthixol  
Clopidogrel  
Cloprostenol  
Clorazepate  
Clorexolone  
Clorprenaline  
Clostebol  
Clostridiopeptidase A  
Clotiazepam  
Clotrimazole  
Cloxacillin

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SECOND SCHEDULE — *continued*

Cloxacillin benzathine  
Cloxazolam  
Cloxiquine  
Clozapine  
Cobicistat  
Codeine  
Co-dergocrine mesylate  
Colchicine  
Colestipol  
Colimycin  
Colistin  
Corifollitropin alfa  
Corticarelin  
Cortisone  
Crisantaspase  
Crizotinib  
Cropropamide  
Crotethamide  
Cyclandelate  
Cyclarbamate  
Cyclizine  
Cyclobarbitone  
Cyclofenil  
Cyclopenthiiazide  
Cyclopentolate  
Cyclophosphamide  
Cycloserine  
Cyclosporin  
Cyclothiazide

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SECOND SCHEDULE — *continued*

Cycrimine

Cyproheptadine

Cyproterone

Cytarabine

Dabigatran etexilate mesylate

Dabrafenib

Dacarbazine

Daclatasvir

Daclizumab

Dactinomycin

Dalfopristin

Dalteparin

Danazol

Danthron

Dantrolene

Dapagliflozin

Dapoxetine

Dapsone

Daptomycin

Darbepoetin alfa

Darunavir

Dasabuvir

Dasatinib

Daunorubicin

Debrisoquine

Deferasirox

Deferiprone

Deferoxamine

Degarelix

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SECOND SCHEDULE — *continued*

Dehydroemetine

Dehydroepiandrosterone (DHEA)

Delapril

Delmadinone

Delorazepam

Demecarium

Demeclocycline

Demoxytocin

Denosumab

Deoxycortone

Deptropine

Deserpidine

Desferrioxamine mesylate

Desfluorotriamcinolone

Desflurane

Desipramine

Deslanoside

Desloratadine

Desmopressin

Desogestrel

Desomorphine

Desonide

Desoxymethasone

Desvenlafaxine

Dexamethasone

Dexamphetamine

Dextimide

Dexfenfluramine

Dexketoprofen

SECOND SCHEDULE — *continued*

Dexlansoprazole  
Dexmedetomidine  
Dexrazoxane  
Dextromethorphan  
Dextromoramide  
Dextropropoxyphene  
Dextrophan  
Dextrothyroxine sodium  
Diacetylmorphine  
Diacetylnalorphine  
Diamorphine  
Diampromide  
Diazepam  
Diazoxide  
Dibekacin  
Dibenzepin  
Dibucaine  
Dichloralphenazone  
Dichlorophenarsine  
Dichlorphenamide  
Diclofenac  
Dicloxacillin  
Didanosine  
Dienoestrol  
Dienogest  
Diethanolamine fusidate  
Diethylcarbamazine  
Diethylthiambutene  
Difenoxin



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SECOND SCHEDULE — *continued*

Diflucortolone  
Diflunisal  
Digoxin  
Dihydralazine  
Dihydroartemisin  
Dihydrocodeine  
Dihydrocodeinone  
Dihydroergotamine  
Dihydroergotoxine  
Dihydroetorphine  
Dihydromorphine  
Dihydrostreptomycin  
Diloxanide  
Diltiazem  
Dimenhydrinate  
Dimercaprol  
Dimethindene  
Dimethisoquin  
Dimethisterone  
Dimethothiazine  
Dimethoxanate  
Dimethpyrindene  
Dimethyl 4-sulphamoylphenyl phosphorothioate  
Dimethyl sulphoxide  
Dimethylthiambutene  
Dimethyltubocurarine  
Dinitronaphthols  
Dinitrothymols  
Dinoprost

SECOND SCHEDULE — *continued*

Dinoprostone  
Dioxaphetyl butyrate  
Diperodon  
Diphenidol  
Diphenylpyraline  
Dipipanone  
Dipivefrin  
Diprophylline  
Dipyridamole  
Dipyrone  
Dirithromycin  
Disopyramide  
Distigmine  
Disulfiram  
Disulphamide  
Dithienylallylamines; dithienyl-alkylallylamines  
Dobutamine  
Docetaxel  
Dolutegravir  
Domperidone  
Donepezil  
Dopamine  
Doripenem  
Dorzolamide  
Dothiepin  
Doxapram  
Doxazosin  
Doxepin  
Doxofylline

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SECOND SCHEDULE — *continued*

Doxorubicin  
Doxycycline  
Doxylamine  
Dronedarone  
Droperidol  
Drospirenone  
Drostanolone  
Drotebanol  
Drotrecogin alfa  
Duloxetine  
Dutasteride  
Dydrogesterone  
Dyflos  
Ebastine  
Econazole  
Ecothiopate iodide  
Ectylurea  
Eculizumab  
Edoxudine  
Edrophonium  
Efalizumab  
Efavirenz  
Eletriptan  
Eltrombopag olamine  
Elvitegravir  
Embramine  
Embutramide  
Emedastine  
Emepronium

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SECOND SCHEDULE — *continued*

Emtricitabine  
Emylcamate  
Enalapril  
Enalaprilat  
Encainide  
Enflurane  
Enfuvirtide  
Enoxaparin  
Entacapone  
Entecavir  
Enzalutamide  
Eperisone  
Ephedrine; its optical isomers  
Epicillin  
Epimestrol  
Epinastine  
Epioestriol  
Epirubicin  
Epithiazide  
Eplerenone  
Epoetin alfa  
Epoetin beta  
Epoprostenol  
Eprosartan  
Eptacog alfa  
Eptifibatide  
Erdosteine  
Ergometrine  
Ergotamine

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SECOND SCHEDULE — *continued*

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  
Ethionamide  
Ethisterone  
Ethoglucid  
Ethoheptazine  
Ethopropazine  
Ethosuximide

SECOND SCHEDULE — *continued*

Ethotoin  
Ethyl biscoumacetate  
Ethyl loflazepate  
Ethyl p-piperidinoacetylaminobenzoate  
Ethylacetanilide  
Ethylmorphine  
Ethylnoradrenaline  
Ethylloestrenol  
Ethylstibamine  
Ethinodiol  
Etidronic acid  
Etilamfetamine  
Etodolac  
Etofenamate  
Etofibrate  
Etofylline clofibrate  
Etomidate  
Etonitazene  
Etonogestrel  
Etoposide  
Etoricoxib  
Etorphine  
Etoxeridine  
Etravirine  
Etretinate  
Everolimus  
Exametazime  
Exemestane  
Exenatide

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SECOND SCHEDULE — *continued*

Ezetimibe  
Famciclovir  
Famotidine  
Fampridine  
Famprofazone  
Fazadinium  
Febuxostat  
Felbinac  
Felodipine  
Felypressin  
Fencamfamin  
Fenclofenac  
Fenetylline  
Fenfluramine  
Fenofibrate  
Fenoprofen  
Fenoterol  
Fenoverine  
Fenpipramide  
Fenpiprane  
Fenproporex  
Fentanyl  
Fenticonazole  
Feprazone  
Ferric carboxymaltose  
Ferucarbotran  
Fexofenadine  
Filgrastim  
Finasteride

SECOND SCHEDULE — *continued*

Fingolimod  
Flavomycin  
Flavoxate  
Flecainide  
Flibanserin  
Floxuridine  
Fluanisone  
Fluclorolone  
Flucloxacillin  
Fluconazole  
Flucytosine  
Fludarabine phosphate  
Fludiazepam  
Fludrocortisone  
Flufenamic acid  
Flugestone  
Flumazenil  
Flumedroxone  
Flumethasone  
Flumethiazide  
Flunisolide  
Flunitrazepam  
Fluocinolone  
Fluocinonide  
Fluocortolone  
Flupromazine  
Fluoro-2-deoxy-d-glucose  
Fluoroacetamide  
Fluoroacetanilide



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SECOND SCHEDULE — *continued*

Fluorometholone  
Fluorouracil  
Fluothane  
Fluoxetine  
Fluoxymesterone  
Flupenthixol  
Fluperolone  
Fluphenazine  
Fluprednidene  
Fluprednisolone  
Fluprostenol  
Flurandrenolone  
Flurazepam  
Flurbiprofen  
Fluspirilene  
Flutamide  
Fluticasone  
Fluvastatin  
Fluvoxamine  
Follicle stimulating hormone (FSH)  
Follitropin alfa  
Fondaparinux  
Formestane  
Formosulphathiazole  
Formoterol  
Fosamprenavir  
Fosaprepitant dimeglumine  
Foscarnet  
Fosfestrol

SECOND SCHEDULE — *continued*

Fosfomycin  
Fosinopril  
Fotemustine  
Framycetin  
Frusemide  
Ftorafur  
Fulvestrant  
Fumagillin  
Furaltadone  
Furazolidone  
Furethidine  
Fusafungine  
Fusidic acid  
Gabapentin  
Gadobenate dimeglumine  
Gadobutrol  
Gadodiamide  
Gadopentetic acid  
Gadoteric acid  
Gadoversetamide  
Gadoxetate  
Gadoxetic acid  
Galantamine  
Gallamine  
Gallium  
Ganciclovir  
Ganirelix  
Gatifloxacin  
Gefitinib

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SECOND SCHEDULE — *continued*

Gemcitabine  
Gemeprost  
Gemfibrozil  
Gemtuzumab ozogamicin  
Gentamicin  
Gestodene  
Gestrinone  
Gestronol  
Gimeracil  
Glafenine  
Glibenclamide  
Glibornuride  
Gliclazide  
Glimepiride  
Glipizide  
Gliquidone  
Glucagon  
Glutethimide  
Glyceryl trinitrate  
Glycopyrrolate  
Glycopyrronium  
Glymidine  
Golimumab  
Gonadorelin  
Goserelin  
Gramicidins  
Granisetron  
Grepafloxacin  
Griseofulvin

SECOND SCHEDULE — *continued*

Guanethidine

Guanoclor

Guanoxan

Hachimycin

Halazepam

Halcinonide

Halofantrine

Halometasone

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

Haloprogin

Halothane

Haloxazolam

Heparin

Heparin calcium

Heptabarbitalone

Heptaminol

Hexamethonium

Hexamethylmelamine

Hexapropymate

Hexobarbitalone

Hexoestrol

Histrelin

Histrelin acetate

Homatropine

Homochlorcyclizine

Hydralazine

Hydrochlorothiazide

Hydrocodone

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SECOND SCHEDULE — *continued*

Hydrocortisone  
Hydromorphenol  
Hydromorphone  
Hydroquinone  
Hydroxychloroquine  
Hydroxycinchoninic  
Hydroxyprogesterone  
Hydroxyquinoline  
Hydroxyurea  
Hydroxyzine  
Hygromycin B  
Hyoscine  
Ibacinabine  
Ibandronic acid  
Ibrutinib  
Ibuprofen  
Idarubicin  
Idelalisib  
Idoxuridine  
Idrocilamide  
Idursulfase  
Ifenprodil  
Ifosfamide  
Iloprost  
Imatinib  
Imidapril  
Imiglucerase  
Imipenem  
Imipramine

SECOND SCHEDULE — *continued*

Imiquimod  
Indacaterol  
Indapamide  
Indinavir  
Indium pentetreotide  
Indobufen  
Indomethacin  
Infliximab  
Interferons  
Iodixanol  
Iodine-131  
Ipilimumab  
Ipratropium  
Iprindole  
Iproniazid  
Irbesartan  
Irinotecan  
Isepamicin  
Isoaminile  
Isocarboxazid  
Isoconazole  
Isoetharine  
Isoflurane  
Isomethadone (isoamidone)  
Isoniazid  
Isoprenaline  
Isopropamide  
Isopyrin  
Isosorbide

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SECOND SCHEDULE — *continued*

Isothipendyl

Isotretinoin

Isoxicam

Isoxsuprine

Isradipine

Itopride

Itraconazole

Ivabradine

Ivermectin

Ixabepilone

Kanamycin

Kanendomycin

Ketamine

Ketanserin

Ketazolam

Ketobemidone

Ketoconazole

Ketoprofen

Ketorolac

Ketotifen

Labetalol

Lacidipine

Lacosamide

Lafutidine

Lamivudine

Lamotrigine

Lanreotide

Lansoprazole

Lanthanum carbonate hydrate

SECOND SCHEDULE — *continued*

Lapatinib  
Laronidase  
Laropiprant  
L-Asparaginase  
Latanoprost  
Laudexium  
Ledipasvir  
Lefetamine  
Leflunomide  
Lenalidomide  
Lenograstim  
Lepirudin  
Lercanidipine  
Letrozole  
Leucovorin  
Leuprorelin  
Levamisole  
Levamphetamine  
Levetiracetam  
Levobunolol  
Levocabastine  
Levocetirizine  
Levodopa  
Levofloxacin  
Levomethamphetamine  
Levomethorphan  
Levomoramide  
Levonorgestrel  
Levorphanol



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SECOND SCHEDULE — *continued*

Levosimendan  
Levothyroxine  
Lidoflazine  
Lignocaine  
Linagliptin  
Lincomycin  
Linezolid  
Liothyronine sodium  
Liraglutide  
Lisinopril  
Lisuride  
Lithium carbonate  
Lixisenatide  
Lodoxamide  
Lofentanil  
Lofepramine  
Lomefloxacin  
Lomustine  
Lonazolac  
Lopinavir  
Loprazolam  
Loracarbef  
Lorazepam  
Lormetazepam  
Losartan  
Loteprednol  
Lovastatin  
Loxoprofen  
L-Pyroglutamyl-L-histidyl-L-proline amide

SECOND SCHEDULE — *continued*

Lumefantrine  
Luteinising hormone  
Lutropin alfa  
Lymecycline  
Lynoestrenol  
Lypressin  
Lysuride  
Macitentan  
Mafenide  
Mangafodipir  
Mannitol hexantrate  
Mannomustine  
Maprotiline  
Maraviroc  
Mazindol  
Mebanazine  
Mebezonium  
Mebhydrolin  
Mebutamate  
Mecamylamine  
Meclastine  
Meclofenamic acid  
Meclofenoxate  
Mecloqualone  
Meclozine  
Medazepam  
Medigoxin  
Medrogestone  
Medroxyprogesterone

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SECOND SCHEDULE — *continued*

Mefenamic acid  
Mefenorex  
Mefloquine  
Mefruside  
Megestrol  
Meglumine gadoterate  
Melengestrol  
Melitracen  
Meloxicam  
Melphalan  
Memantine  
Menotrophin  
Mepenzolate  
Mephenesin  
Mephentermine  
Mepivacaine  
Meprobamate  
Mepyramine  
Mequitazine  
Mercaptopurine; derivatives of mercaptopurine  
Meropenem  
Mesalazine  
MESNA (2-mercaptoethane sulfonate sodium)  
Mesocarb  
Mesoridazine  
Mestanolone  
Mesterolone  
Mestranol  
Metabutethamine

SECOND SCHEDULE — *continued*

Metaiodobenzylguanidine (I-131)

Metaraminol

Metaxalone

Metazocine

Metergoline

Metformin

Methacycline

Methadone (amidone)

Methadyl acetate

Methallenoestril

Methandienone

Methandriol

Methanthelinium bromide

Methapyrilene

Methaqualone

Metharbitone

Methdilazine

Methenolone

Methicillin

Methimazole

Methisoprinol

Methixene

Methocarbamol

Methohexitone

Methoin

Methoserpidine

Methotrexate

Methotrimeprazine

Methoxamine

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SECOND SCHEDULE — *continued*

Methoxsalen  
Methoxyflurane  
Methoxyphenamine  
Methsuximide  
Methyclothiazide  
Methyl 5-aminolevulinate hydrochloride  
Methylaminoheptane  
Methylamphetamine  
Methyldihydromorphine  
Methyldopa  
Methyldopate  
Methylephedrine  
Methylergometrine  
Methylnaltrexone bromide  
Methylpentynol  
Methylphenidate  
Methylphenobarbitone  
Methylprednisolone  
Methylsulphonal  
Methyltestosterone  
Methylthiouracil  
Methypyrone  
Methysergide  
Metipranolol  
Metoclopramide  
Metolazone  
Metomidate  
Metopon  
Metoprolol

SECOND SCHEDULE — *continued*

Metronidazole  
Mexiletine  
Mianserin  
Mibefradil  
Micafungin  
Miconazole  
Micronomicin  
Midazolam  
Midecamycin  
Midodrine  
Miglitol  
Milrinone  
Miltefosine  
Minaprine  
Minocycline  
Minoxidil  
Mirabegron  
Mirtazapine  
Misoprostol  
Mithramycin  
Mitobronitol  
Mitomycins  
Mitopodozide  
Mitotane  
Mitoxantrone  
Mivacurium  
Mizolastine  
m-Nitrophenol; o-Nitrophenol; p-Nitrophenol  
Moclobemide

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SECOND SCHEDULE — *continued*

Moexipril  
Molgramostim  
Molindone  
Mometasone  
Monofluoroacetic acid  
Montelukast  
Morazone  
Morinamide  
Moroctocog alfa  
Moroxydine  
Morphine methylbromide; morphine N-oxide and other pentavalent nitrogen  
morphine derivatives  
Moxalactam  
Moxifloxacin  
Moxonidine  
Mupirocin  
Muromonab-CD3  
Mustine and any other N-substituted derivatives of di-(2-chloroethyl) amine  
Mycophenolic acid  
Myrophine  
Myrtecaine  
Nabumetone  
N-Acetylaspartyl glutamic acid sodium salt  
Nadolol  
Nadroparin  
Nafarelin  
Nafcillin  
Naftidrofuryl  
Naftifine

SECOND SCHEDULE — *continued*

Nalbuphine  
Nalidixic acid  
Nalmefene  
Nalorphine  
Naloxone  
Naltrexone  
Nandrolone  
Naproxen  
Naratriptan  
Natalizumab  
Natamycin  
Nateglinide  
N-Benzoyl sulphanilamide  
Nealbarbitone  
Nebivolol  
Nedocromil  
Nefazodone  
Nefopam  
Nelfinavir  
Neoarsphenamine  
Neomycin  
Neostigmine  
Nepafenac  
Netilmicin  
Nevirapine  
Nialamide  
Niaprazine  
Nicardipine  
Nicergoline



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SECOND SCHEDULE — *continued*

Nicocodine  
Nicodicodine  
Nicomorphine  
Nicotinic acid  
Nicoumalone  
Nifedipine  
Nifuroxazide  
Nifurzide  
Nikethamide  
Nilotinib  
Nilvadipine  
Nimesulide  
Nimetazepam  
Nimodipine  
Nimorazole  
Nintedanib  
Niridazole  
Nisoldipine  
Nitrazepam  
Nitrendipine  
Nitric oxide  
Nitrofurantoin  
Nitrofurazone  
Nitromin  
Nitroprusside  
Nitroxoline  
Nizatidine  
Nomegestrol  
Nometasone

SECOND SCHEDULE — *continued*

Nomifensine  
Nonacog alfa  
Noracymethadol  
Noradrenaline  
Noramidopyrine  
Norbuprenorphine  
Norcodeine  
Nordazepam  
Norelgestromin  
Norethandrolone  
Norethisterone  
Norethynodrel  
Norfloxacin  
Norgestimate  
Norgestrel  
Norketamine  
Norlevorphanol  
Normethadone  
Normorphine  
Norpipanone  
Nortriptyline  
Novobiocin  
Noxythiolin  
Nystatin  
Obinutuzumab  
Ocriplasmin  
Octacosactrin  
Octocog alfa  
Octreotide

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SECOND SCHEDULE — *continued*

Oestradiol  
Oestriol  
Oestrone  
Ofatumumab  
Ofloxacin  
Olanzapine  
Oleandomycin  
Olmesartan  
Olodaterol  
Olopatadine  
Olsalazine  
Omalizumab  
Ombitasvir  
Omeprazole  
Ondansetron  
Opi Pramol  
Orciprenaline  
Orlistat  
Ornidazole  
Orphenadrine  
Orthocaine  
Oseltamivir  
Oteracil  
Oxaliplatin  
Oxamniquine  
Oxandrolone  
Oxantel  
Oxatomide  
Oxazepam

SECOND SCHEDULE — *continued*

Oxazolam  
Oxcarbazepine  
Oxedrine  
Oxidronic acid  
Oxiracetam  
Oxolinic acid  
Oxomemazine  
Oxophenarsine  
Oxpentifylline  
Oxprenolol  
Oxybuprocaine  
Oxybutynin  
Oxycodone  
Oxymesterone  
Oxymetazoline  
Oxymetholone  
Oxymorphone  
Oxypertine  
Oxyphenbutazone  
Oxyphencyclimine  
Oxyphenonium  
Oxytetracycline  
Oxytocin  
p-Aminobenzoic acid  
Paclitaxel  
Paliperidone  
Palivizumab  
Palonosetron  
Pamidronate

SECOND SCHEDULE — *continued*

p-Aminobenzene-sulphonamide

Pancuronium

Panitumumab

Pantoprazole

Paraldehyde

Paramethadione

Paramethasone

Parecoxib

Pargyline

Paricalcitol

Paritaprevir

Parnaparin

Paromomycin

Paroxetine

Pasireotide

Pazopanib

Pecilocin

Pefloxacin

Pegaptanib

Pegfilgrastim

Peginterferon

Pegvisomant

Pembrolizumab

Pemetrexed

Pemoline

Pempidine

Penamcillin

Penciclovir

Penethamate

SECOND SCHEDULE — *continued*

Penfluridol

Penicillamine

Penicillin G; benzylpenicillin

Penicillin V; phenoxymethylpenicillin

Pentaerythritol tetranitrate

Pentamidine

Pentazocine

Penthienate

Pentobarbitone

Pentolinium

Pentoxifylline

Perampanel

Perfluoropropane

Pergolide

Perhexiline

Pericyazine

Perindopril

Perphenazine

Pertuzumab

Pethidine

Pethidinic acid

Phenacaine

Phenacemide

Phenacetin

Phenaglycodol

Phenazocine

Phenbenicillin

Phenbutrazate

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SECOND SCHEDULE — *continued*

Phencyclidine  
Phendimetrazine  
Phenelzine  
Phenethicillin  
Phenethylamine  
Phenetidylphenacetin  
Pheneturide  
Phenformin  
Phenglutarimide  
Phenindamine  
Phenindione  
Pheniramine  
Phenmetrazine  
Phenobarbitone  
Phenoperidine  
Phenothiazine  
Phenoxybenzamine  
Phenoxypropazine  
Phenprocoumon  
Phensuximide  
Phentermine  
Phentolamine  
Phenylbutazone  
Phenylmethyl barbituric acid  
Phenylpropanolamine  
Phenytoin  
Phthalylsulphacetamide  
Phthalylsulphathiazole  
Physostigmine

SECOND SCHEDULE — *continued*

Picrotoxin  
Pilocarpine  
Pimecrolimus  
Piminodine  
Pimozide  
Pinazepam  
Pioglitazone  
Pipecuronium  
Pipemidic acid  
Pipenzolate  
Piperacillin  
Piperazine oestrone sulphate  
Piperidolate  
Pipothiazine  
Pipradrol  
Piracetam  
Pirenoxine  
Pirenzepine  
Piribedil  
Piritramide  
Piroxicam  
Pirprofen  
Pivmecillinam  
Pizotifen  
Plerixafor  
Poldine methysulphate  
Polidexide  
Polymethylene-bis(trimethylammonium) salts  
Polymyxins



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SECOND SCHEDULE — *continued*

Polyoestradiol

Polythiazide

Pomalidomide

Posaconazole

Practolol

Pralatrexate

Pralidoxime

Pramipexole

Prasugrel

Pravastatin

Prazepam

Praziquantel

Prazosin

Prednicarbate

Prednisolone

Prednisone

Pregabalin

Prenoxdiazine

Prenylamine

Prilocaine

Procaine

Primaquine

Primidone

Prindolol

Probenecid

Probucol

Procainamide

Procaine penicillin

Procarbazine

SECOND SCHEDULE — *continued*

Prochlorperazine  
Procyclidine  
Profenone  
Progesterone  
Proguanil  
Prolintane  
Promazine  
Promestriene  
Promethazine  
Promoxolane  
Pronethalol  
Propafenone  
Propanidid  
Propantheline  
Proparacaine  
Propicillin  
Propiomazine  
Propiram  
Propiverine  
Propofol  
Propoxyphene  
Propranolol  
Propylhexedrine  
Propylthiouracil  
Propyromazine  
Proquamezine  
Proquazone  
Prostaglandins  
Protamine sulphate

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SECOND SCHEDULE — *continued*

Prothionamide  
Prothipendyl  
Protirelin  
Protriptyline  
Proxymetacaine  
Proxiphylline  
Prucalopride  
Pyrathiazine  
Pyrazinamide  
Pyridinolcarbamate  
Pyridostigmine  
Prymethamine  
Pyritinol  
Pyrovalerone  
Pyrrobutamine  
Quetiapine  
Quinagolide  
Quinalbarbitone  
Quinapril  
Quinestradol  
Quinestrol  
Quinethazone  
Quinidine  
Quinine  
Quinupristin  
Rabeprazole  
Racecadotril  
Racemethorphan  
Racemoramide

SECOND SCHEDULE — *continued*

Racemorphan

Radium-223 chloride

Rafoxanide

Raloxifene

Raltegravir

Raltitrexed

Ramipril

Ranibizumab

Ranitidine

Ranolazine

Rasburicase

Raubasine

Razoxane

Reboxetine

Regorafenib

Remifentanyl

Repaglinide

Reserpine

Retapamulin

Reteplase

Retigabine

Retinoic acid

Reviparin

Rhodamine B

Ribavirin

Rifamide

Rifampicin

Rifaximin

Rilmenidine

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SECOND SCHEDULE — *continued*

Rilpivirine  
Riluzole  
Rimexolone  
Rimiterol  
Riociguat  
Risedronic acid  
Risperidone  
Ristocetin  
Ritodrine  
Ritonavir  
Rituximab  
Rivaroxaban  
Rivastigmine  
Rizatriptan  
Rocuronium  
Rofecoxib  
Rolitetracycline  
Romiplostim  
Ropinirole  
Ropivacaine  
Rosiglitazone  
Rosoxacin  
Rosuvastatin  
Rotigotine  
Roxatidine  
Roxithromycin  
Rupatadine  
Ruxolitinib  
Sacubitril

SECOND SCHEDULE — *continued*

Salazosulphadimidine

Salbutamol

Salmefamol

Salmeterol

Santonin

Saquinavir

Saxagliptin

Secbutobarbitone

Secnidazole

Secobarbital

Secukinumab

Selegiline

Sermorelin

Sertaconazole

Sertraline

Sevelamer

Sevoflurane

Sibutramine

Sildenafil

Siltuximab

Silver sulphadiazine

Simfibrate

Simvastatin

Sirolimus

Sisomicin

Sitagliptin

Sodium apolate

Sodium aurothiomalate

Sodium dihydroazapentacene

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SECOND SCHEDULE — *continued*

Sodium fluoride  
Sodium iodide [I-131]  
Sodium molybdate  
Sodium oxidronate  
Sodium pertechnetate  
Sodium picosulphate  
Sodium tetradecyl sulphate  
Sodium valproate  
Sofosbuvir  
Solifenacin  
Somatostatin  
Somatropin  
Sorafenib  
Sotalol  
Sparfloxacin  
Spectinomycin  
Spiramycin  
Spironolactone  
Stanolone  
Stanozolol  
Stavudine  
Stilboestrol  
Streptokinase  
Streptomycin and its derivatives  
Streptozocin  
Strontium [89Sr]  
Styramate  
Succinylsulphathiazole  
Sucroferric oxyhydroxide

SECOND SCHEDULE — *continued*

Sufentanil  
Sugammadex  
Sulbactam  
Sulbenicillin  
Sulfabenzamide  
Sulfacytine  
Sulfametopyrazine  
Sulfametrole  
Sulindac  
Sulphabromomethazine  
Sulphacetamide  
Sulphachlorpyridazine  
Sulphadiazine  
Sulphadicramide  
Sulphadimethoxine  
Sulphadimidine  
Sulphadoxine  
Sulphaethidole  
Sulphafurazole  
Sulphaguanidine  
Sulphaloxic acid  
Sulphamerazine  
Sulphamethazine  
Sulphamethizole  
Sulphamethoxazole  
Sulphamethoxydiazine  
Sulphamethoxypyridazine  
Sulphametopyrazine  
Sulphamonomethoxine



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SECOND SCHEDULE — *continued*

Sulphamoxole  
Sulphanilamide  
Sulphaphenazole  
Sulphapyrazole  
Sulphapyridine  
Sulphaquinoxaline  
Sulphasalazine  
Sulphasomidine  
Sulphathiazole  
Sulphathiourea  
Sulphatolamide  
Sulphaurea  
Sulphinpyrazone  
Sulphomyxin  
Sulphonals; alkyl sulphonals  
Sulpiride  
Sulprostone  
Sultamicillin  
Sulthiame  
Sumatriptan  
Sunitinib  
Suprofen  
Suxamethonium  
Suxethonium bromide  
Syrosingopine  
Tacrine  
Tacrolimus  
Tadalafil  
Tafluprost

SECOND SCHEDULE — *continued*

Talampicillin  
Tamoxifen  
Tamsulosin  
Tapentadol  
Tazarotene  
Tazobactam  
Teclothiazide  
Tedizolid  
Tegafur  
Tegaserod  
Teicoplanin  
Telbivudine  
Telithromycin  
Telmisartan  
Temazepam  
Temozolomide  
Temsilolimus  
Tenecteplase  
Teniposide  
Tenofovir  
Tenonitrozele  
Tenoxicam  
Terazosin  
Terbinafine  
Terbutaline  
Terconazole  
Terfenadine  
Teriflunomide  
Teriparatide

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SECOND SCHEDULE — *continued*

Terlipressin  
Tertatolol  
Testosterone  
Tetrabenazine  
Tetracaine  
Tetracosactide  
Tetracyclines  
Tetrahydrocannabinol  
Tetrazepam  
Tetrofosmin  
Thalidomide  
Thallium  
Thebacon  
Thenalidine  
Thenyldiamine  
Theofibrate  
Theophylline  
Thiabendazole  
Thiacetazone  
Thialbarbitone  
Thiamazole  
Thiambutosine  
Thiamphenicol  
Thiazinamium methylsulphate  
Thiethylperazine  
Thiocarlide  
Thioguanine  
Thiopentone  
Thiopropazate

SECOND SCHEDULE — *continued*

Thiopropazine

Thioridazine

Thiotepa

Thiothixene

Thiouracil; its alkyl derivatives

Thymalfasin

Thymoxamine

Thyroid gland, the active principles of

Thyrotrophin

Thyroxine

Tiagabine

Tianeptine

Tiapride

Tiaprofenic acid

Tibolone

Ticagrelor

Ticarcillin

Ticlopidine

Tiemonium

Tigecycline

Tigloidine

Tilidine

Tiludronic acid

Timepidium

Timolol

Tinidazole

Tinzaparin

Tioconazole

Tiotropium

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SECOND SCHEDULE — *continued*

Tirilazad  
Tirofiban  
Tixocortol  
Tizanidine  
Tobramycin  
Tocainide  
Tocilizumab  
Tofacitinib  
Tofenacin  
Tolazamide  
Tolazoline  
Tolbutamide  
Tolcapone  
Tolmetin  
Toloxatone  
Tolperisone  
Tolpropamine  
Tolterodine  
Topiramate  
Topotecan  
Toremifene  
Tosufloxacin  
Trabectedin  
Tramadol  
Tranexamic acid  
Tranlycypromine  
Trastuzumab  
Travoprost  
Trazodone

SECOND SCHEDULE — *continued*

Treosulphan  
Tretamine  
Tretinoin  
Triacetylleandomycin  
Triamcinolone  
Triamterene  
Triaziquone  
Triazolam  
Tribenoside  
Tribromethyl alcohol  
Trichomycin  
Triclofos sodium  
Tricyclamol  
Trienbolone  
Trientine  
Trifluoperazine  
Trifluorothymidine  
Trifluperidol  
Trifluridine  
Triflusal  
Trihexyphenidyl  
Trimebutine  
Trimegestone  
Trimeperidine  
Trimeprazine  
Trimetaphan  
Trimetazidine  
Trimethoprim  
Trimetrexate

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SECOND SCHEDULE — *continued*

Trimipramine  
Trimustine  
Tripamide  
Tripeleennamine  
Triptorelin  
Tromantadine  
Tropicamide  
Tropisetron  
Trosium  
Trovafloracin  
Troloxone  
Tubocurarine  
Tybamate  
Tylosin  
Ulipristal  
Umeclidinium  
Unoprostone  
Uramustine  
Urapidil  
Urea  
Ureamycin  
Urethane  
Urokinase  
Ursodeoxycholic acid  
Ustekinumab  
Valaciclovir  
Valdecoxib  
Valganciclovir  
Valproic acid

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SECOND SCHEDULE — *continued*

Valsartan  
Vancomycin  
Vardenafil  
Varenicline  
Vasopressin  
Vecuronium  
Vedolizumab  
Vemurafenib  
Venlafaxine  
Verapamil  
Vernakalant  
Verteporfin  
Vidarabine  
Vigabatrin  
Vildagliptin  
Viloxazine  
Vinbarbitone  
Vinblastine  
Vincristine  
Vindesine  
Vinflunine  
Vinorelbine  
Vinpocetine  
Vinylbital  
Viomycin  
Virginiamycin  
Vismodegib  
Voriconazole  
Vortioxetine



SECOND SCHEDULE — *continued*

Warfarin  
Xamoterol  
Xipamide  
Xylazine  
Xylometazoline  
Yttrium-90 chloride  
Zafirlukast  
Zalcitabine  
Zanamivir  
Zidovudine  
Zipeprol  
Ziprasidone  
Zofenopril  
Zolendronic acid  
Zolmitriptan  
Zolpidem  
Zopiclone  
Zoxazolamine  
Zuclopenthixol

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

## PART 2

## CLASSES OF THERAPEUTIC PRODUCTS

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

SECOND SCHEDULE — *continued*

## PART 3

## ACTIVE INGREDIENTS IN PHARMACY-ONLY MEDICINES

Albendazole  
Alverine  
Amorolfine  
Amyl nitrite  
Bambuterol  
Benzydamine  
Brompheniramine  
Buclizine  
Butyl aminobenzoate  
Carbinoxamine  
Carbocysteine  
Cetirizine  
Cinnarizine  
Dexchlorpheniramine  
Dicycloverine  
Diphenhydramine  
Diphenoxylate  
Flunarizine  
Levodropropizine  
Loperamide  
Loratadine  
Mebendazole  
Mebeverine  
Naphazoline  
Nicotine  
Oxethazaine  
Parachlorophenol

SECOND SCHEDULE — *continued*

Phenyltoloxamine  
 Pholcodine  
 Podophyllum resin  
 Podophyllotoxin  
 Policresulen  
 Procaterol  
 Pseudoephedrine  
 Sodium cromoglycate  
 Tetrahydrozoline  
 Tolnaftate  
 Triprolidine  
 Tyrothricin

## THIRD SCHEDULE

Regulations 11(d) and 12(b)		
<i>First column</i>	<i>Second column</i>	<i>Third column</i>
<i>Class of persons</i>	<i>Type of prescription-only medicine</i>	<i>Conditions</i>
1. The owner or the master of a ship which does not carry a doctor on board as part of her crew	All prescription-only medicines	The supply must be necessary for the treatment of persons on the ship
2. Persons requiring prescription-only medicines for the purpose of enabling them, in the course of any business carried on by them, to comply with any requirements made by or under any written law with respect to the	Such prescription-only medicines as specified in the relevant written law	The supply — (a) must be for the purpose of enabling the persons to comply with any requirements made by or under any written law; and (b) is subject to such conditions and is to be made in such

THIRD SCHEDULE — *continued*

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

## FOURTH SCHEDULE

Regulation 20(2)

<i>First column</i>	<i>Second column</i>
<i>Substance</i>	<i>Term to be used</i>
1. Tartrazine	tartrazine (Code E102)

FOURTH SCHEDULE — *continued*

<i>First column</i>	<i>Second column</i>
<i>Substance</i>	<i>Term to be used</i>
	tartrazine (Code 102)
	tartrazine (Code FD and C Yellow No. 5)
2. Benzoic acid	benzoic acid
	benzoic acid (Code E210)
3. Sodium benzoate	sodium benzoate
	sodium benzoate (Code E211)

## FIFTH SCHEDULE

Regulation 20(3)

## CAUTIONARY INFORMATION TO BE LABELLED ON THERAPEUTIC PRODUCTS

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

FIFTH SCHEDULE — *continued*

<i>First column</i>	<i>Second column</i>
<i>Therapeutic product</i>	<i>Cautionary information</i>
Buclicine	
Carbinoxamine	
Chlorcyclizine	
Chlorpheniramine	
Cinnarizine	
Clemastine	
Clemizole	
Cyclizine	
Cyproheptadine	
Dexchlorpheniramine	
Dimethpyrindene	
Diphenhydramine	
Diphenylpyraline	
Doxylamine	
Embramine	
Flunarizine	
Homochlorcyclizine	
Isothipendyl	
Levocabastine	
Mebhydrolin	
Meclastine	
Meclozine	
Mepyramine	
Mequitazine	
Methdilazine	
Oxatomide	
Oxomemazine	

FIFTH SCHEDULE — *continued*

<i>First column</i>	<i>Second column</i>
<i>Therapeutic product</i>	<i>Cautionary information</i>
Phenindamine	
Pheniramine	
Phenyltoloxamine	
Promethazine	
Pyrathiazine	
Pyrrobutamine	
Thenalidine	
Thenyldiamine	
Thiazinamium	
Tolpropamine	
Tripeleennamine	
Triprolidine	

## SIXTH SCHEDULE

[Deleted by S 458/2022 wef 01/07/2022]

## SEVENTH SCHEDULE

<i>First column</i>	<i>Second column</i>
<i>Therapeutic product</i>	<i>Maximum amount allowed</i>
1. Codeine; its salts	<p>Regulation 52(1)(b)</p> <p>(a) Oral liquid preparation — not exceeding 15 mg per 5 ml and not exceeding 240 ml in quantity</p> <p>(b) Solid preparation — not exceeding 30 mg per dosage unit and not exceeding 20 dosage units in quantity</p>

SEVENTH SCHEDULE — *continued*

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

[S 732/2021 wef 01/10/2021]

Made on 14 July 2016.

KANDIAH SATKUNANANTHAM  
*Chairman,*  
*Health Sciences Authority,*  
*Singapore.*

[HSA 401:04/05-000; HSA/LPPD/711:12/61-000; AG/LLRD/SL/  
122D/2010/13 Vol. 12]

(To be presented to Parliament under section 72(5) of the Health Products Act).