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**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:

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;

[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;

- (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;

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- (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;
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- (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;
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- (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

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- (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

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(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]

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;

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- (b) the appropriate quantitative particulars of any active ingredient of the therapeutic product;
 - (c) an appropriate control number, such as a serial number, batch number or lot number;
 - (d) the expiry date of the therapeutic product;
 - (e) where the therapeutic product is registered, the registration number assigned to the registered therapeutic product by the Authority.
- (2) Where a therapeutic product contains any substance specified in the first column of the Fourth Schedule, the therapeutic product must be labelled with a statement declaring the presence of that substance, and that substance may be described by a corresponding term specified in the second column of that Schedule.
- (3) Where a therapeutic product contains any substance specified in the first column of the Fifth Schedule, the therapeutic product must be labelled with the caution set out in the second column of that Schedule.
- (4) Where a therapeutic product is contained in a container, which is in the form of a bubble, blister or other sealed unit and is part of a continuous series comprising a sheet or strip of like containers, paragraph (2) or (3), as the case may be, is taken to have been complied with if the statement mentioned in paragraph (2) or the caution mentioned in paragraph (3) is printed or displayed or otherwise marked in a prominent position at frequent intervals on the sheet or strip of the container.
- (5) All information accompanying the therapeutic product mentioned in paragraph (1), including the statement mentioned in paragraph (2) and the caution mentioned in paragraph (3) —
- (a) must be provided in English; and
 - (b) must be legible and indelible.

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

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

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

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

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

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

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

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

PART 5

REGISTRATION OF THERAPEUTIC PRODUCTS

Requirements for registration

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

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

Whether therapeutic product subject to patent

23.—(1) In dealing with an application for the registration of a therapeutic product, the Authority must consider whether a patent under the Patents Act 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.

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(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

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(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.

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(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

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- (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,

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).

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(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).

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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

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

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

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

Duty to notify Authority concerning recall

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

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

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

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

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

Division 2 — Duties specific to licensees

Duty of licensed manufacturer

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

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

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

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

Duty of licensed importer

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

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

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

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

Duty of licensed wholesaler

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

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

Responsible person

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

(2) The licensee must ensure that —

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

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

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

Offence for contravention of duties

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

Changes affecting licence

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

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

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

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

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

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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

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.

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(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.

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(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

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.

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(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).

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(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).

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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

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.

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Division 2 — Licensed retail pharmacies

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

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

- (a) the therapeutic product is compounded from an active ingredient or another therapeutic product;
- (b) the final form or packaging of the compounded therapeutic product is not available or marketed for commercial supply in Singapore;
- (c) the compounding is carried out —
 - (i) at the licensed retail pharmacy;
 - (ii) by a qualified pharmacist or a person acting under the supervision of a qualified pharmacist;
 - (iii) for the purposes and under the conditions described in paragraph (2), (3) or (4), whichever is applicable; and
 - (iv) in the case of a sterile therapeutic product, at premises where standards established for the operation of clean rooms and the preparation of

sterile products are in place and properly documented; and

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

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

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

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(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

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

Division 6 — Other exceptions

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

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

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

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

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

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

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

Therapeutic products for research or non-clinical purposes

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

(a) is solely for —

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

(ii) a non-clinical purpose; and

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

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

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

PART 8

EXCEPTIONS — SUPPLY OF THERAPEUTIC PRODUCTS WITHOUT REGISTRATION

Prescribed exceptions

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

(a) the supply of a therapeutic product compounded 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;

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(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

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);

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- (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);

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- (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;

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- (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;

- (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]

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

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]

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

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

Amineptine

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

Aminorex

Amobarbital

Barbital

FIRST SCHEDULE — *continued*

Bromazepam
Brotizolam
Butalbital
Butobarbital
Camazepam
Cathine
Chlordiazepoxide
Clobazam
Clonazepam
Clonazolam
Clorazepate
Clotiazepam
Cloxazolam
Cyclobarbital
Delorazepam
Diazepam
Diclazepam
Estazolam
Ethchlorvynol
Ethinamate
Ethyl loflazepate
Etilamfetamine
Etizolam
Fencamfamin
Fenproporex
Flualprazolam
Flubromazolam
Fludiazepam
Flurazepam

FIRST SCHEDULE — *continued*

Glutethimide
Halazepam
Haloxazolam
Ketazolam
Lefetamine
Loprazolam
Lorazepam
Lormetazepam
Mazindol
Medazepam
Mefenorex
Meprobamate
Mesocarb
Methylphenobarbital
Methypylon
Midazolam
Nitrazepam
Nordazepam
Oxazepam
Oxazolam
Pemoline
Pentazocine
Pentobarbital
Phenazepam
Phenobarbital
Phentermine
Pinazepam
Prazepam
Secbutabarbital

FIRST SCHEDULE — *continued*

Temazepam

Tetrazepam

Vinylbital

Zolpidem

[S 681/2023 wef 01/11/2023]

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

[S 681/2023 wef 01/11/2023]

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

SECOND SCHEDULE

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

PART 1

ACTIVE INGREDIENTS IN PRESCRIPTION-ONLY MEDICINES

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

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

2-Phenylcinchoninic acid; 2-salicylcinchoninic acid

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

5-Phenylhydantoin

Abacavir

Abatacept

Abciximab

Abemaciclib

Abiraterone

Abrocitinib

Acalabrutinib

Acamprosate

Acarbose

Acebutolol

SECOND SCHEDULE — *continued*

Aceclofenac
Acemetacin
Acepromazine
Acetanilide
Acetanilide; alkyl acetanilides
Acetazolamide
Acetohexamide
Acetorphine
Acetylcarbromal
Acetylcysteine
Acetyldigoxin
Acetyldihydrocodeine
Acetylmethadol
Acetylstrophanthidin
Acipimox
Acitretin
Aclidinium
Acrivastine
Actinomycins
Acyclovir
Adalimumab
Adapalene
Adefovir
Adicillin
Adiphenine
Adrenaline
Adrenocorticotrophic hormone (ACTH)
Afatinib
Aflibercept

SECOND SCHEDULE — *continued*

Agalsidase alfa
Agalsidase beta
Agomelatine
Alatrofloxacin
Albutrepenonacog alfa
Alcaftadine
Alclofenac
Alclometasone
Alcuronium
Aldesleukin
Aldosterone
Alectinib
Alefcept
Alemtuzumab
Alendronic acid
Alfacalcidol
Alfentanil
Alfuzosin
Algestone
Alglucosidase alfa
Alirocumab
Aliskiren
Allobarbitone
Allopurinol
Allylisopropylacetylurea
Allyloestrenol
Allylprodine
Alminoprofen
Almitrine

SECOND SCHEDULE — *continued*

Alogliptin

Alosetron

Alpelisib

Alphacalcidol

[*Deleted by S 681/2023 wef 01/11/2023*]

Alphacetylmethadol

Alphachloralose

Alphadolone

Alphameprodine

Alphamethadol

Alphaprodine

Alphaxalone

Alprazolam

Alprenolol

Alprostadil

Alseroxylon

Alteplase

Altretamine

Amantadine

Amбенonium

Ambrisentan

Ambroxol

Ambuside

Ambutonium

Ametazole

Amethocaine

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

Amidopyrine

Amifostine

SECOND SCHEDULE — *continued*

Amikacin
Amiloride
Amineptine
Aminocaproic acid
Aminoglutethimide
Aminolevulinic acid
Aminophylline
Aminopterin
Aminorex
Amiodarone
Amisulpride
Amitriptyline
Amivantamab
Amlodipine
Ammonium lactate
Amoxycillin
Amphetamine
Amphotycin
Amphotericin B
Ampicillin
Amprenavir
Amrinone
Amsacrine (M-AMSA)
Amylobarbitone
Amylocaine
Anagrelide
Anastrozole
Ancrod
Androsterone

SECOND SCHEDULE — *continued*

Angiotensin amide

Anidulafungin

Anileridine

Anistreplase

Antazoline

Apalutamide

Apixaban

Apomorphine

Apraclonidine

Apramycin

Apremilast

Aprepitant

Aprobarbitone

Aprotinin

Aripiprazole

Arotinolol

Arsenic trioxide

Arsphenamine

Arteether

Artemether

Artemisinin

Artesunate

Articaine

Asciminib

Asenapine

Aspoxicillin

Astemizole

Asunaprevir

Atazanavir

SECOND SCHEDULE — *continued*

Atenolol
Atezolizumab
Atomoxetine
Atorvastatin
Atosiban
Atovaquone
Atracurium
Atropine
Auranofin
Avanafil
Avelumab
Avibactam
Axitinib
Azacitidine
Azacyclonol
Azaperone
Azapropazone
Azasetron
Azatadine
Azathioprine
Azelaic acid
Azelastine
Azidamphenicol
Azidocillin
Azilsartan
Azithromycin
Aztreonam
Bacampicillin
Bacitracin

SECOND SCHEDULE — *continued*

Baclofen
Baloxavir marboxil
Bambermycin
Bamipine
Barbitone
Barbituric acid
Baricitinib
Basiliximab
Becaplermin
Beclamide
Beclomethasone
Befunolol
Bekanamycin
Belantamab mafodotin
Belimumab
Bemegride
Benactyzine
Benactyzine; its quarternary compounds
Benapryzine
Benazepril
Bendamustine
Bendamustine hydrochloride
Bendrofluazide
Benethamine penicillin
Benfluorex
Benoxaprofen
Benperidol
Benralizumab
Benserazide

SECOND SCHEDULE — *continued*

Benzamidosalicylic acid
Benzathine penicillin
Benzbromarone
Benzethidine
Benzhexol
Benzilonium
Benzocaine
Benzoctamine
Benzoestrol
Benzphetamine
Benzquinamide
Benzthiazide
Benztropine
Benztropine and its homologues
Benzylfentanyl
Benzylmorphine
Benzylpenicillin
Besifloxacin
Betahistine
Betameprodine
Betamethadol
Betamethasone
Betaprodine
Betaxolol
Bethanechol
Bethanidine
Betiatide
Bevacizumab
Bevonium

SECOND SCHEDULE — *continued*

Bevonium methyl sulphate

Bezafibrate

Bezitramide

Bicalutamide

Bicisate

Bicisate dihydrochloride

Bictegravir

Bifonazole

Bilastine

Bimatoprost

Biperiden

Bisoprolol

Bleomycin

Blinatumomab

Boceprevir

Boldenone undecenoate

Bopindolol

Bortezomib

Bosentan

Botulinum toxin

Brentuximab

Bretylium

Brexipiprazole

Brigatinib

Brimonidine

Brinzolamide

Brolamfetamine

Bromazepam

Bromhexine

SECOND SCHEDULE — *continued*

Bromocriptine
Bromodiphenhydramine
Bromvaletone
Brotizolam
Budesonide
Bufexamac
Buflomedil
Buformin
Bumadizone calcium
Bumetanide
Bunazosin
Buphenine
Buphenine hydrochloride
Bupivacaine
Bupranolol
Buprenorphine
Bupropion
Burosumab
Buserelin
Buspirone
Busulphan
Butacaine
Butalbital
Butamirate
Butanilicaine
Butizide
Butobarbitone
Butoconazole
Butriptyline

SECOND SCHEDULE — *continued*

Butropium
Butropium bromide
Butylchloral hydrate
Cabazitaxel
Cabergoline
Cabimicina
Cabotegravir
Cabozantinib
Calcipotriol
Calcitonin
Calcitriol
Calcium barbiturate
Calcium carbimide
Calcium dobesilate
Calfactant
Camazepam
Canagliflozin
Canakinumab
Candesartan
Candicidin
Capecitabine
Capmatinib
Capreomycin
Captodiamine
Captopril
Caramiphen
Carbachol
Carbamazepine
Carbenicillin

SECOND SCHEDULE — *continued*

Carbenoxolone
Carbetocin
Carbidopa
Carbimazole
Carboplatin
Carboprost
Carbromal
Carbutamide
Carfecillin
Carfentanil
Carfilzomib
Cariprazine
Carisoprodol
Carmustine
Carperidine
Carprofen
Carteolol
Carvedilol
Caspofungin
Cathine
Cathinone
Cefaclor
Cefadroxil
Cefamandole
Cefatrizine
Cefdinir
Cefepime
Cefixime
Cefodizime

SECOND SCHEDULE — *continued*

Cefoperazone
Cefotaxime
Cefotiam
Cefoxitin
Cefpirome
Cefprozil
Cefsulodin
Ceftaroline
Ceftazidime
Ceftibuten
Ceftizoxime
Ceftolozane
Ceftriaxone
Cefuroxime
Celecoxib
Cephalexin
Cephaloglycin
Cephaloram
Cephaloridine
Cephalothin
Cephazolin
Cephradine
Ceritinib
Cerivastatin
Certolizumab
Cetrorelix
Cetuximab
Chenodeoxycholic acid
Chloral hydrate

SECOND SCHEDULE — *continued*

Chlorambucil
Chloramphenicol
Chlorcyclizine
Chlordiazepoxide
Chlormadinone
Chlormerodrin
Chlormethiazole
Chlormezanone
Chlormidazole
Chlorothiazide
Chloroquine
Chlorpheniramine
Chlorphenoxamine
Chlorphentermine
Chlorpromazine
Chlorpropamide
Chlorprothixene and other derivatives of 9-methylenethiazanthene
Chlorquinaldol
Chlortetracycline
Chlorthalidone and other derivatives of o-chlorobenzene sulphonamide
Chlorzoxazone
Cholestyramine
Choline Theophyllinate
Chorionic gonadotrophin
Chromium [51CR]
Chromium [51CR] Edetate
Chromomycin A
Ciclacillin
Ciclesonide

SECOND SCHEDULE — *continued*

Ciclopirox
Cilastatin
Cilazapril
Cilostazol
Cimetidine
Cinacalcet
Cinchocaine
Ciprofibrate
Ciprofloxacin
Cisapride
Cisatracurium
Cisplatin
Citalopram
Citicoline
Cladribine
Clarithromycin
Clavulanic acid
Clebopride
Clemastine
Clemizole
Clenbuterol
Clidinium
Clindamycin
Clioquinol
Clobazam
Clobenzorex
Clobetasol
Clobetasone
Clobutinol

SECOND SCHEDULE — *continued*

Clodronic acid
Clofarabine
Clofazimine
Clofedanol
Clofibrate
Clomiphene
Clomipramine
Clomocycline
Clonazepam
Clonazepam
Clonidine
Clonitazene
Clopamide
Clopenthixol
Clopidogrel
Cloprostenol
Clorazepate
Clorexolone
Clorprenaline
Clostebol
Clostridiopeptidase A
Clotiazepam
Clotrimazole
Cloxacillin
Cloxacillin benzathine
Cloxazolam
Cloxiquine
Clozapine
Cobicistat

SECOND SCHEDULE — *continued*

Cobimetinib
Codeine
Co-dergocrine mesylate
Colchicine
Colestipol
Colimycin
Colistin
Corifollitropin alfa
Corticorelin
Cortisone
Crisaborole
Crisantaspase
Crizotinib
Cropropamide
Crotethamide
Cyclandelate
Cyclarbamate
Cyclizine
Cyclobarbitone
Cyclofenil
Cyclopenthiazide
Cyclopentolate
Cyclophosphamide
Cycloserine
Cyclosporin
Cyclothiazide
Cycrimine
Cyproheptadine
Cyproterone

SECOND SCHEDULE — *continued*

Cytarabine

Dabigatran

Dabigatran etexilate mesylate

Dabrafenib

Dacarbazine

Daclatasvir

Daclizumab

Dacomitinib

Dactinomycin

Dalfopristin

Dalteparin

Danazol

Danthron

Dantrolene

Dapagliflozin

Dapoxetine

Dapsone

Daptomycin

Daratumumab

Darbepoetin alfa

Darolutamide

Darunavir

Dasabuvir

Dasatinib

Daunorubicin

Davesomeran

Debrisoquine

Deferasirox

Deferiprone

SECOND SCHEDULE — *continued*

Deferoxamine
Degarelix
Dehydroemetine
Dehydroepiandrosterone (DHEA)
Delapril
Delmadinone
Delorazepam
Demecarium
Demeclocycline
Demoxytocin
Denosumab
Deoxycholic acid
Deoxycortone
Deptropine
Deserpidine
Desferrioxamine mesylate
[Deleted by S 681/2023 wef 01/11/2023]
Desfluorotriamcinolone
Desflurane
Desipramine
Deslanoside
Desloratadine
Desmopressin
Desogestrel
Desomorphine
Desonide
Desoxymethasone
Desvenlafaxine
Dexamethasone

SECOND SCHEDULE — *continued*

Dexamphetamine

Dexetimide

Dexfenfluramine

Dexketoprofen

Dexlansoprazole

Dexmedetomidine

Dexrazoxane

Dextromethorphan

[Deleted by S 681/2023 wef 01/11/2023]

Dextromoramide

Dextropropoxyphene

Dextrophan

Dextrothyroxine

Dextrothyroxine sodium

Diacetylmorphine

Diacetylnalorphine

Diamorphine

Diampromide

Diazepam

Diazoxide

Dibekacin

Dibenzepin

Dibucaine

Dichloralphenazone

Dichlorophenarsine

Dichlorphenamide

Diclazepam

Diclofenac

Dicloxacillin

SECOND SCHEDULE — *continued*

Didanosine

Dienoestrol

Dienogest

Diethanolamine fusidate

[Deleted by S 681/2023 wef 01/11/2023]

Diethylcarbamazine

Diethylthiambutene

Difelikefalin

Difenoxin

Diflucortolone

Diflunisal

Digoxin

Dihydralazine

Dihydroartemisin

Dihydrocodeine

Dihydrocodeinone

Dihydroergotamine

Dihydroergotoxine

Dihydroetorphine

Dihydromorphine

Dihydrostreptomycin

Diloxanide

Diltiazem

Dimenhydrinate

Dimercaprol

Dimethindene

Dimethisoquin

Dimethisterone

Dimethothiazine

SECOND SCHEDULE — *continued*

Dimethoxanate
Dimethpyrindene
Dimethyl 4-sulphamoylphenyl phosphorothioate
Dimethyl fumarate
Dimethyl sulphoxide
Dimethylthiambutene
Dimethyltubocurarine
Dinitronaphthols
Dinitrothymols
Dinoprost
Dinoprostone
Dioxaphetyl butyrate
Diperodon
Diphenidol
Diphenylpyraline
Dipipanone
Dipivefrin
Diprophylline
Dipyridamole
Dipyrone
Dirithromycin
Disopyramide
Distigmine
Disulfiram
Disulphamide
Dithienylallylamines
Dithienylallylamines; dithienyl-alkylallylamines
Dobutamine
Docetaxel

SECOND SCHEDULE — *continued*

Dolutegravir
Domperidone
Donepezil
Dopamine
Doravirine
Doripenem
Dorzolamide
Dostarlimab
Dothiepin
Doxapram
Doxazosin
Doxepin
Doxofylline
Doxorubicin
Doxycycline
Doxylamine
Dronedarone
Droperidol
Drospirenone
Drostanolone
Drotebanol
Drotrecogin alfa
Dulaglutide
Duloxetine
Dupilumab
Durvalumab
Dutasteride
Dydrogesterone
Dyflos

SECOND SCHEDULE — *continued*

Ebastine
Econazole
Ecothiopate
Ecothiopate iodide
Ectylurea
Eculizumab
Edoxaban
Edoxudine
Edrophonium
Efalizumab
Efavirenz
Elasomeran
Elbasvir
Eletriptan
Eltrombopag
Eltrombopag olamine
Elvitegravir
Embramine
Embutramide
Emedastine
Emepronium
Emicizumab
Empagliflozin
Emtricitabine
Emylcamate
Enalapril
Enalaprilat
Encainide
Enflurane

SECOND SCHEDULE — *continued*

Enfortumab vedotin
Enfuvirtide
Enoxaparin
Entacapone
Entecavir
Entrectinib
Enzalutamide
Eperisone
Ephedrine
Ephedrine; its optical isomers
Epicillin
Epimestrol
Epinastine
Epioestriol
Epirubicin
Epithiazide
Eplerenone
Epoetin alfa
Epoetin beta
Epoprostenol
Eprosartan
Eptacog alfa
Eptifibatide
Eptinezumab
Eravacycline
Erdafitinib
Erdosteine
Erenumab
Ergometrine

SECOND SCHEDULE — *continued*

Ergotamine
Ergotoxine
Eribulin
Eribulin mesylate
Erlotinib
Ertapenem
Ertugliflozin
Erythrityl tetranitrate
Erythromycin
Erythropoietin
Escitalopram
Esketamine
Esmolol
Esomeprazole
Estazolam
Estramustine
Etafedrine
Etanercept
Etelcalcetide
Ethacrynic acid
Ethambutol
Ethamivan
Ethamsylate
Ethchlorvynol
Ethebenecid
Ethiazide
Ethinamate
Ethinyloestradiol
Ethionamide

SECOND SCHEDULE — *continued*

Ethisterone
Ethoglucid
Ethoheptazine
Ethopropazine
Ethosuximide
Ethotoin
Ethyl biscoumacetate
Ethyl loflazepate
Ethyl p-piperidinoacetylaminobenzoate
Ethylacetanilide
Ethylmorphine
Ethylnoradrenaline
Ethyloestrenol
Ethylstibamine
Ethinodiol
Etidronic acid
Etilamfetamine
Etizolam
Etodolac
Etofenamate
Etofibrate
Etofylline
Etofylline clofibrate
Etomidate
Etonitazene
Etonogestrel
Etoposide
Etoricoxib
Etorphine

SECOND SCHEDULE — *continued*

Etoxeridine
Etravirine
Etretinate
Everolimus
Evolocumab
Exametazime
Exemestane
Exenatide
Ezetimibe
Famciclovir
Famotidine
Fampridine
Famprofazone
Famtozinameran
Faricimab
Fazadinium
Febuxostat
Fedratinib
Felbinac
Felodipine
Felypressin
Fencamfamin
Fenclofenac
Fenetylline
Fenfluramine
Fenofibrate
Fenoprofen
Fenoterol
Fenoverine

SECOND SCHEDULE — *continued*

Fenpipramide
Fenpiprane
Fenproporex
Fentanyl
Fenticonazole
Feprazone
Ferric carboxymaltose
Ferric derisomaltose
Ferucarbotran
Fexofenadine
Filgrastim
Fimasartan
Finasteride
Finerenone
Fingolimod
Flavomycin
Flavoxate
Flecainide
Flibanserin
Floxuridine
Flualprazolam
Fluanisone
Flubromazolam
Fluclorolone
Flucloxacillin
Fluconazole
Flucytosine
Fludarabine
Fludarabine phosphate

SECOND SCHEDULE — *continued*

Fludiazepam
Fludrocortisone
Flufenamic acid
Flugestone
Flumazenil
Flumedroxone
Flumethasone
Flumethiazide
Flunisolide
Flunitrazepam
Fluocinolone
Fluocinonide
Fluocortolone
Flupromazine
Fluoro-2-deoxy-d-glucose
Fluoroacetamide
Fluoroacetanilide
Fluorometholone
Fluorouracil
Fluothane
Fluoxetine
Fluoxymesterone
Flupenthixol
Fluperolone
Fluphenazine
Fluprednidene
Fluprednisolone
Fluprostenol
Flurandrenolone

SECOND SCHEDULE — *continued*

Flurazepam
Flurbiprofen
Fluspirilene
Flutamide
Flutemetamol
Fluticasone
Fluvastatin
Fluvoxamine
Follicle stimulating hormone (FSH)
Follitropin alfa
Follitropin delta
Fondaparinux
Formestane
Formosulphathiazole
Formoterol
Fosamprenavir
Fosaprepitant
Fosaprepitant dimeglumine
Foscarnet
Fosfestrol
Fosfomycin
Fosinopril
Fotemustine
Framycetin
Fremanezumab
Frusemide
Ftorafur
Fulvestrant
Fumagillin

SECOND SCHEDULE — *continued*

Furaltadone

Furazolidone

Furethidine

Fusafungine

Fusidic acid

Gabapentin

Gadobenic acid

Gadobenate dimeglumine

Gadobutrol

Gadodiamide

Gadopentetic acid

Gadoteric acid

Gadoversetamide

Gadoxetate

[Deleted by S 681/2023 wef 01/11/2023]

Gadoxetic acid

Galantamine

Galcanezumab

Gallamine

Gallium

Ganciclovir

Ganirelix

Gatifloxacin

Gefitinib

Gemcitabine

Gemeprost

Gemfibrozil

Gemtuzumab ozogamicin

Gentamicin

SECOND SCHEDULE — *continued*

Gestodene
Gestrinone
Gestronol
Gilteritinib
Gimeracil
Glafenine
Glecaprevir
Glibenclamide
Glibornuride
Gliclazide
Glimepiride
Glipizide
Gliquidone
Glucagon
Glutethimide
Glyceryl trinitrate
Glycopyrrolate
Glycopyrronium
Glymidine
Golimumab
Gonadorelin
Goserelin
Gramicidins
Granisetron
Grazoprevir
Grepafloxacin
Griseofulvin
Guanethidine
Guanoclor

SECOND SCHEDULE — *continued*

Guanoxan

Guselkumab

Hachimycin

Halazepam

Halcinonide

Halofantrine

Halometasone

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

Haloproglin

Halothane

Haloxazolam

Heparin

Heparin calcium

Heptabarbitalone

Heptaminol

Hexamethonium

Hexamethylmelamine

Hexapropymate

Hexobarbitalone

Hexoestrol

Histrelin

[Deleted by S 681/2023 wef 01/11/2023]

Histrelin acetate

Homatropine

Homochlorcyclizine

Hydralazine

Hydrochlorothiazide

Hydrocodone

SECOND SCHEDULE — *continued*

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

SECOND SCHEDULE — *continued*

Imipramine

Imiquimod

Inclisiran

Indacaterol

Indapamide

Indinavir

Indium pentetreotide

Indobufen

Indomethacin

Infliximab

Inotuzumab ozogamicin

Interferons

Iodixanol

Iodine-131

Ioflupane

Ipilimumab

Ipratropium

Iprindole

Iproniazid

Irbesartan

Irinotecan

Isatuximab

Isavuconazonium

Isepamicin

Isoaminile

Isocarboxazid

Isoconazole

[Deleted by S 681/2023 wef 01/11/2023]

Isoetharine

SECOND SCHEDULE — *continued*

Isoflurane

Isomethadone (isoamidone)

Isoniazid

Isoprenaline

Isopropamide

Isopyrin

Isosorbide

Isothipendyl

Isotretinoin

Isoxicam

Isoxsuprine

Isradipine

Itopride

Itraconazole

Ivabradine

Ivermectin

Ixabepilone

Ixazomib

Ixekizumab

Kanamycin

Kanendomycin

Ketamine

Ketanserin

Ketazolam

Ketobemidone

Ketoconazole

Ketoprofen

Ketorolac

Ketotifen

SECOND SCHEDULE — *continued*

Labetalol
Lacidipine
Lacosamide
Lafutidine
Lamivudine
Lamotrigine
Lanreotide
Lansoprazole
Lanthanum carbonate
Lanthanum carbonate hydrate
Lapatinib
Laronidase
Laropiprant
Larotrectinib
L-Asparaginase
Latanoprost
Latanoprostene
Laudexium
Ledipasvir
Lefetamine
Leflunomide
Lemborexant
Lenalidomide
Lenograstim
Lenvatinib
Lepirudin
Lercanidipine
Letermovir
Letrozole

SECOND SCHEDULE — *continued*

Leucovorin

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Leuprorelin

Levamisole

Levamphetamine

Levetiracetam

Levobunolol

Levocabastine

Levocetirizine

Levodopa

Levofloxacin

Levomethamphetamine

Levomethorphan

Levomoramide

Levonorgestrel

Levorphanol

Levosimendan

Levothyroxine

Lidoflazine

Lignocaine

Linagliptin

Lincomycin

Linezolid

Lipegfilgrastim

Liothyronine

Liothyronine sodium

Liraglutide

Lisdexamfetamine

Lisinopril

SECOND SCHEDULE — *continued*

Lisuride
Lithium carbonate
Lixisenatide
Lodoxamide
Lofentanil
Lofepamine
Lomefloxacin
Lomustine
Lonazolac
Lonocog alfa
Lopinavir
Loprazolam
Loracarbef
Lorazepam
Lorlatinib
Lormetazepam
Losartan
Loteprednol
Lovastatin
Loxoprofen
L-Pyroglutamyl-L-histidyl-L-proline amide
Lubiprostone
Luliconazole
Lumefantrine
Lurasidone
Lurbinectedin
Luspatercept
Luteinising hormone
Lutetium-177

SECOND SCHEDULE — *continued*

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

SECOND SCHEDULE — *continued*

Mefenorex

Mefloquine

Mefruside

Megestrol

Meglumine gadoterate

[Deleted by S 681/2023 wef 01/11/2023]

Melengestrol

Melitracen

Meloxicam

Melphalan

Memantine

Menotrophin

Mepenzolate

Mephenesin

Mephentermine

Mepivacaine

Mepolizumab

Meprobamate

Mepyramine

Mequitazine

Mercaptopurine

Mercaptopurine; derivatives of mercaptopurine

Meropenem

Mesalazine

MESNA (2-mercaptoethane sulfonate sodium)

Mesocarb

Mesoridazine

Mestanolone

Mesterolone

SECOND SCHEDULE — *continued*

Mestranol

Metabutethamine

Metaiodobenzylguanidine (I-131)

Metaraminol

Metaxalone

Metazocine

Metergoline

Metformin

Methacycline

Methadone

Methadone (amidone)

Methadyl acetate

Methallenoestril

Methandienone

Methandriol

Methantheline

Methanthelinium bromide

Methapyrilene

Methaqualone

Metharbitone

Methdilazine

Methenolone

Methicillin

Methimazole

Methisoprinol

Methixene

Methocarbamol

Methohexitone

Methoin

SECOND SCHEDULE — *continued*

Methoserpidine
Methotrexate
Methotrimeprazine
Methoxamine
Methoxsalen
Methoxyflurane
Methoxyphenamine
Methsuximide
Methyclothiazide
Methyl aminolevulinate
Methyl 5-aminolevulinate hydrochloride
Methylaminoheptane
Methylamphetamine
Methyldihydromorphine
Methyldopa
Methyldopate
Methylephedrine
Methylergometrine
Methylnaltrexone
Methylnaltrexone bromide
Methylpentynol
Methylphenidate
Methylphenobarbitone
Methylprednisolone
Methylsulphonal
Methyltestosterone
Methylthioninium
Methylthiouracil
Methyprylone

SECOND SCHEDULE — *continued*

Methysergide

Metipranolol

Metoclopramide

Metolazone

Metomidate

Metopon

Metoprolol

Metronidazole

Mexiletine

Mianserin

Mibefradil

Micafungin

Miconazole

[*Deleted by S 681/2023 wef 01/11/2023*]

Micronomicin

Midazolam

Midecamycin

Midodrine

Midostaurin

Mifepristone

Miglitol

Milrinone

Miltefosine

Minaprine

Minocycline

Minoxidil (other than topical preparations)

Minoxidil

Mirabegron

Mirtazapine

SECOND SCHEDULE — *continued*

Misoprostol
Mithramycin
Mitobronitol
Mitomycins
Mitopodozide
Mitotane
Mitoxantrone
Mivacurium
Mizolastine
m-Nitrophenol; o-Nitrophenol; p-Nitrophenol
Moclobemide
Moexipril
Molgramostim
Molindone
Mometasone
Monofluoroacetic acid
Montelukast
Morazone
Morinamide
Moroctocog alfa
Moroxydine
Morphine
Morphine methylbromide; morphine N-oxide and other pentavalent nitrogen
morphine derivatives
Moxalactam
Moxifloxacin
Moxonidine
Mupirocin
Muromonab-CD3

SECOND SCHEDULE — *continued*

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

Mycophenolic acid

Myrophine

Myrtecaine

Nabumetone

N-Acetylaspartyl glutamic acid; spaglumatic acid

N-Acetylaspartyl glutamic acid sodium salt

Nadolol

Nadroparin

Nafarelin

Nafcillin

Naftidrofuryl

Naftifine

Nalbuphine

Nalidixic acid

Nalmefene

Nalorphine

Naloxone

Naltrexone

Nandrolone

Naproxen

Naratriptan

Natalizumab

Natamycin

Nateglinide

N-Benzoyl sulphanilamide

[Deleted by S 681/2023 wef 01/11/2023]

Nealbarbitone

Nebivolol

SECOND SCHEDULE — *continued*

Necitumumab

Nedocromil

Nefazodone

Nefopam

Nelfinavir

Neoarsphenamine

Neomycin

Neostigmine

Nepafenac

Neratinib

Netarsudil

Netilmicin

Netupitant

Nevirapine

Nialamide

Niaprazine

Nicardipine

Nicergoline

Nicocodine

Nicodicodine

Nicomorphine

Nicotinic acid

[Deleted by S 681/2023 wef 01/11/2023]

Nicoumalone

Nifedipine

Nifuroxazide

Nifurzide

Nikethamide

Nilotinib

SECOND SCHEDULE — *continued*

Nilvadipine
Nimesulide
Nimetazepam
Nimodipine
Nimorazole
Nintedanib
Niraparib
Niridazole
Nisoldipine
Nitrazepam
Nitrendipine
Nitric oxide
Nitrofurantoin
Nitrofurazone
Nitromin
Nitroprusside
Nitroxoline
Nivolumab
Nizatidine
Nomegestrol
Nometasone
Nomifensine
Nonacog alfa
Noracymethadol
Noradrenaline
Noramidopyrine
Norbuprenorphine
Norcodeine
Nordazepam

SECOND SCHEDULE — *continued*

Norelgestromin
Norethandrolone
Norethisterone
Norethynodrel
Norfloxacin
Norgestimate
Norgestrel
Norketamine
Norlevorphanol
Normethadone
Normorphine
Norpipanone
Nortriptyline
Novobiocin
Noxythiolin
Nusinersen
Nystatin
Obinutuzumab
Ocriplasmin
Octacosactrin
Octocog alfa
Octreotide
Oestradiol
Oestriol
Oestrone
Ofatumumab
Ofloxacin
Olanzapine
Olaparib

SECOND SCHEDULE — *continued*

Oleandomycin
Olmesartan
Olodaterol
Olopatadine
Olsalazine
Omalizumab
Ombitasvir
Omeprazole
Omidenepag
Ondansetron
Opipramol
Orciprenaline
Orelabrutinib
Orlistat
Ornidazole
Orphenadrine
Orthocaine
Oseltamivir
Osimertinib
Ospemifene
Oteracil
Oxaliplatin
Oxamniquine
Oxandrolone
Oxantel
Oxatomide
Oxazepam
Oxazolam
Oxcarbazepine

SECOND SCHEDULE — *continued*

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

SECOND SCHEDULE — *continued*

p-Aminobenzene-sulphonamide

[Deleted by S 681/2023 wef 01/11/2023]

Pancuronium

Panitumumab

Panobinostat

Pantoprazole

Paraldehyde

Paramethadione

Paramethasone

Parecoxib

Pargyline

Paricalcitol

Paritaprevir

Parnaparin

Paromomycin

Paroxetine

Pasireotide

Pazopanib

Pecilocin

Pefloxacin

Pegaptanib

Pegaspargase

Pegfilgrastim

Peginterferon

Pegvisomant

Pemafibrate

Pembrolizumab

Pemetrexed

Pemoline

SECOND SCHEDULE — *continued*

Pempidine
Penamecillin
Penciclovir
Penethamate
Penfluridol
Penicillamine
Penicillin G; benzylpenicillin

Penicillin V; phenoxymethylpenicillin
Pentaerythritol tetranitrate
Pentamidine
Pentazocine
Penthienate
Pentobarbitone
Pentolinium
Pentoxifylline
Perampanel
Perfluorobutane
Perfluoropropane
Pergolide
Perhexiline
Pericyazine
Perindopril
Perphenazine
Pertuzumab
Pethidine
Pethidinic acid
Phenacaine
Phenacemide

SECOND SCHEDULE — *continued*

Phenacetin
Phenaglycodol
Phenazepam
Phenazocine
Phenbenicillin
Phenbutrazate
Phencyclidine
Phendimetrazine
Phenelzine
Phenethicillin
Phenethylamine
Phenetidylphenacetin
Pheneturide
Phenformin
Phenglutarimide
Phenindamine
Phenindione
Pheniramine
Phenmetrazine
Phenobarbitone
Phenoperidine
Phenothiazine
Phenoxybenzamine
Phenoxypropazine
Phenprocoumon
Phensuximide
Pentamine
Pentolamine
Phenylbutazone

SECOND SCHEDULE — *continued*

Phenylmethyl barbituric acid

Phenylpropanolamine

Phenytoin

Phthalylsulphacetamide

Phthalylsulphathiazole

Physostigmine

Pibrentasvir

Picrotoxin

Pilocarpine

Pimecrolimus

Piminodine

Pimozide

Pinazepam

Pioglitazone

Pipecuronium

Pipemidic acid

Pipenzolate

Piperacillin

Piperazine oestrone sulphate

Piperidolate

Pipothiazine

Pipradrol

Piracetam

Pirenoxine

Pirenzepine

Pirfenidone

Piribedil

Piritramide

Piroxicam

SECOND SCHEDULE — *continued*

Pirprofen
Pitavastatin
Pivmecillinam
Pizotifen
Plerixafor
Polatuzumab vedotin
Poldine
Poldine methysulphate
Polidexide
Polymethylene-bis(trimethylammonium) salts
Polymyxins
Polyoestradiol
Polythiazide
Pomalidomide
Ponatinib
Posaconazole
Practolol
Pralatrexate
Pralidoxime
Pralsetinib
Pramipexole
Prasugrel
Pravastatin
Prazepam
Praziquantel
Prazosin
Prednicarbate
Prednisolone
Prednisone

SECOND SCHEDULE — *continued*

Pregabalin
Prenoxdiazine
Prenylamine
Prilocaine
Procaine
Primaquine
Primidone
Prindolol
Probenecid
Probucol
Procinamide
Procaine penicillin
Procarbazine
Prochlorperazine
Procyclidine
Profenone
Progesterone
Proguanil
Prolintane
Promazine
Promestriene
Promethazine
Promoxolane
Pronethalol
Propafenone
Propanidid
Propantheline
Proparacaine
Propicillin

SECOND SCHEDULE — *continued*

Propiomazine
Propiram
Propiverine
Propofol
Propoxyphene
Propranolol
Propylhexedrine
Propylthiouracil
Propyromazine
Proquamezine
Proquazone
Prostaglandins
Protamine
Protamine sulphate
Prothionamide
Prothipendyl
Protirelin
Protriptyline
Proxymetacaine
Proxyphylline
Prucalopride
Pyrathiazine
Pyrazinamide
Pyridinolcarbamate
Pyridostigmine
Pirimethamine
Pyritinol
Pyrovalerone
Pyrrobutamine

SECOND SCHEDULE — *continued*

Quetiapine
Quinagolide
Quinalbarbitone
Quinapril
Quinestradol
Quinestrol
Quinethazone
Quinidine
Quinine
Quinupristin
Rabeprazole
Racecadotril
Racemethorphan
Racemoramide
Racemorphan
Radium-223
Radium-223 chloride
Rafoxanide
Raloxifene
Raltegravir
Raltitrexed
Ramipril
Ramucirumab
Ranibizumab
Ranitidine
Ranolazine
Rasagiline
Rasburicase
Raubasine

SECOND SCHEDULE — *continued*

Raxtozinameran

Razoxane

Reboxetine

Regorafenib

Remdesivir

Remifentanyl

Repaglinide

Reserpine

Retapamulin

Reteplase

Retigabine

Retinoic acid

Revefenacin

Reviparin

Rhodamine B

Ribavirin

Ribociclib

Rifamide

Rifampicin

Rifapentine

Rifaximin

Rilmenidine

Rilpivirine

Riluzole

Rimegepant

Rimexolone

Rimiterol

Riociguat

Ripasudil

SECOND SCHEDULE — *continued*

Ripretinib
Risankizumab
Risdiplam
Risedronic acid
Risperidone
Ristocetin
Ritodrine
Ritonavir
Rituximab
Rivaroxaban
Rivastigmine
Rizatriptan
Rocuronium
Rofecoxib
Rolitetracycline
Romiplostim
Romosozumab
Ropinirole
Ropivacaine
Rosiglitazone
Rosoxacin
Rosuvastatin
Rotigotine
Roxatidine
Roxithromycin
Rufinamide
Rupatadine
Rurioctocog alfa pegol
Ruxolitinib

SECOND SCHEDULE — *continued*

Sacituzumab govitecan

Sacubitril

Safinamide

Salazosulphadimidine

Salbutamol

Salmefamol

Salmeterol

Santonin

Saquinavir

Sarilumab

Satralizumab

Saxagliptin

Secbutobarbitone

Secnidazole

Secobarbital

Secukinumab

Selegiline

Selexipag

Selinexor

Selumetinib

Semaglutide

Sermorelin

Sertaconazole

Sertraline

Sevelamer

Sevoflurane

Sibutramine

Sildenafil

Siltuximab

SECOND SCHEDULE — *continued*

Silver sulphadiazine

Simeprevir

Simfibrate

Simoctocog alfa

Simvastatin

Siponimod

Sirolimus

Sisomicin

Sitagliptin

Sodium apolate

Sodium aurothiomalate

Sodium dihydroazapentacene

Sodium fluoride

Sodium iodide [I-131]

Sodium molybdate [99Mo]

Sodium molybdate

Sodium oxidronate

Sodium pertechnetate

Sodium picosulphate

Sodium pyrophosphate

Sodium tetradecyl sulphate

Sodium valproate

Sodium zirconium

Sofosbuvir

Solifenacin

Somatostatin

Somatropin

Sorafenib

Sotalol

SECOND SCHEDULE — *continued*

Sotorasib
Sparfloxacin
Spectinomycin
Spiramycin
Spironolactone
Stanolone
Stanozolol
Stavudine
Stilboestrol
Streptokinase
Streptomycin
Streptomycin and its derivatives
Streptozocin
Strontium [89Sr]
Styramate
Succinylsulphathiazole
Sucroferric oxyhydroxide
Sufentanil
Sugammadex
Sulbactam
Sulbenicillin
Sulfabenzamide
Sulfacytine
Sulfametopyrazine
Sulfametrole
Sulindac
Sulphabromomethazine
Sulphacetamide
Sulphachlorpyridazine

SECOND SCHEDULE — *continued*

Sulphadiazine
Sulphadicramide
Sulphadimethoxine
Sulphadimidine
Sulphadoxine
Sulphaethidole
Sulphafurazole
Sulphaguanidine
Sulphaloxic acid
Sulphamerazine
Sulphamethazine
Sulphamethizole
Sulphamethoxazole
Sulphamethoxydiazine
Sulphamethoxypyridazine
Sulphametopyrazine
Sulphamonomethoxine
Sulphamoxole
Sulphanilamide
Sulphaphenazole
Sulphapyrazole
Sulphapyridine
Sulphaquinoxaline
Sulphasalazine
Sulphasomidine
Sulphathiazole
Sulphathiourea
Sulphatolamide
Sulphaurea

SECOND SCHEDULE — *continued*

Sulphinpyrazone

Sulphomyxin

Sulphonal

Sulphonal; alkyl sulphonals

Sulpiride

Sulprostone

Sultamicillin

Sulthiame

Sumatriptan

Sunitinib

Suprofen

Suxamethonium

Suxethonium bromide

Syrosingopine

Tacrine

Tacrolimus

Tadalafil

Tafamidis

Tafluprost

Talampicillin

Talazoparib

Taliglucerase alfa

Tamoxifen

Tamsulosin

Tapentadol

Tazarotene

Tazobactam

Teclothiazide

Tedizolid

SECOND SCHEDULE — *continued*

Tegafur
Tegaserod
Tegoprazan
Teicoplanin
Telbivudine
Telithromycin
Telmisartan
Temazepam
Temozolomide
Temsilolimus
Tenecteplase
Teniposide
Tenofovir
Tenonitroazole
Tenoxicam
Tepotinib
Terazosin
Terbinafine
Terbutaline
Terconazole
Terfenadine
Teriflunomide
Teriparatide
Terlipressin
Tertatolol
Testosterone
Tetrabenazine
Tetracaine
Tetracosactide

SECOND SCHEDULE — *continued*

Tetracyclines
Tetrahydrocannabinol
Tetrazepam
Tetrofosmin
Tezepelumab
Thalidomide
Thallium
Thebacon
Thenalidine
Thenyldiamine
Theofibrate
Theophylline
Thiabendazole
Thiacetazone
Thialbarbitone
Thiamazole
Thiambutosine
Thiamphenicol
Thiazinamium
Thiazinamium methylsulphate
Thiethylperazine
Thiocarlide
Thioguanine
Thiopentone
Thiopropazate
Thiopropazine
Thioridazine
Thiotepa
Thiothixene

SECOND SCHEDULE — *continued*

Thiouracil

Thiouracil; its alkyl derivatives

Thymalfasin

Thymoxamine

Thyroid gland, the active principles of

[*Deleted by S 681/2023 wef 01/11/2023*]

Thyrotrophin

Thyroxine

Tiagabine

Tianeptine

Tiapride

Tiaprofenic acid

Tibolone

Ticagrelor

Ticarcillin

Ticlopidine

Tiemonium

Tigecycline

Tigluidine

Tilidine

Tiludronic acid

Timepidium

Timolol

Tinidazole

Tinzaparin

Tioconazole

Tiotropium

Tipiracil

Tirilazad

SECOND SCHEDULE — *continued*

Tirofiban
Tirzepatide
Tixocortol
Tizanidine
Tobramycin
Tocainide
Tocilizumab
Tofacitinib
Tofenacin
Tolazamide
Tolazoline
Tolbutamide
Tolcapone
Tolmetin
Toloxatone
Tolperisone
Tolpropamine
Tolterodine
Tolvaptan
Topiramate
Topotecan
Toremifene
Tosufloxacin
Tozinameran
Trabectedin
Tramadol
Trametinib
Tranexamic acid
Tranlycypromine

SECOND SCHEDULE — *continued*

Trastuzumab
Travoprost
Trazodone
Treosulphan
Tretamine
Tretinoin
Triacetyloleandomycin
Triamcinolone
Triamterene
Triaziquone
Triazolam
Tribenoside
Tribromethyl alcohol
Trichomycin
Triclofos sodium
Tricyclamol
Trienbolone
Trientine
Trifarotene
Trifluoperazine
Trifluorothymidine
Trifluperidol
Trifluridine
Triflusal
Trihexyphenidyl
Trimebutine
Trimegestone
Trimeperidine
Trimeprazine

SECOND SCHEDULE — *continued*

Trimetaphan
Trimetazidine
Trimethoprim
Trimetrexate
Trimipramine
Trimustine
Tripamide
Tripeleennamine
Triptorelin
Tromantadine
Tropicamide
Tropisetron
Trospium
Trovaflouxacin
Troxidone
Tubocurarine
Tucatinib
Turoctocog alfa
Tybamate
Tylosin
Ulipristal
Umeclidinium
Unoprostone
Upadacitinib
Uramustine
Urapidil
Urea [13C]
Urea [14C]
Urea

SECOND SCHEDULE — *continued*

Ureamycin
Urethane
Urokinase
Ursodeoxycholic acid
Ustekinumab
Valaciclovir
Valbenazine
Valdecoxib
Valganciclovir
Valproic acid
Valsartan
Vancomycin
Vardenafil
Varenicline
Vasopressin
Vecuronium
Vedolizumab
Velaglucerase alfa
Velpatasvir
Vemurafenib
Venetoclax
Venlafaxine
Verapamil
Vericiguat
Vernakalant
Verteporfin
Vidarabine
Vigabatrin
Vilanterol

SECOND SCHEDULE — *continued*

Vildagliptin
Viloxazine
Vinbarbitone
Vinblastine
Vincristine
Vindesine
Vinflunine
Vinorelbine
Vinpocetine
Vinylbital
Viomycin
Virginiamycin
Vismodegib
Vonoprazan
Voriconazole
Vortioxetine
Voxilaprevir
Warfarin
Xamoterol
Xipamide
Xylazine
Xylometazoline
Yttrium-90
Yttrium-90 chloride
Zafirlukast
Zalcitabine
Zanamivir
Zanubrutinib
Zidovudine

SECOND SCHEDULE — *continued*

Zipeprol

Ziprasidone

Zofenopril

Zolendronic acid

Zolmitriptan

Zolpidem

Zopiclone

Zoxazolamine

Zuclopenthixol

Note: The stereoisomeric forms or salts of the substances specified in Part 1, wherever the existence of such stereoisomeric forms or salts is possible, are also active ingredients for the purpose of this Part.

[S 681/2023 wef 01/11/2023]

[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. Vaccine antigens

[S 681/2023 wef 01/11/2023]

PART 3

ACTIVE INGREDIENTS IN PHARMACY-ONLY MEDICINES

Albendazole

Alverine

Amorolfine

SECOND SCHEDULE — *continued*

Amyl nitrite
Bambuterol
Benzydamine
Brompheniramine
Buclizine
Butyl aminobenzoate
Carbinoxamine
Carbocysteine
Cetirizine
Cinnarizine
Dexchlorpheniramine
Dextromethorphan
Dicycloverine
Diphenhydramine
Diphenoxylate
Flunarizine
Isoconazole
Levodropropizine
Loperamide
Loratadine
Mebendazole
Mebeverine
Miconazole
Naphazoline
Nicotine
Oxethazaine
Parachlorophenol
Phenyltoloxamine
Pholcodine

SECOND SCHEDULE — *continued*

Podophyllum resin

Podophyllotoxin

Policresulen

Procaterol

Pseudoephedrine

Sodium cromoglycate

Tetrahydrozoline

Tolnaftate

Triprolidine

Tyrothricin

Note: The stereoisomeric forms or salts of the substances specified in Part 3, wherever the existence of such stereoisomeric forms or salts is possible, are also active ingredients for the purpose of this Part.

[S 681/2023 wef 01/11/2023]

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	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

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>
by or under any written law with respect to the medical treatment of their employees		(b) is subject to such conditions and is to be made in such circumstances as specified in the relevant written law
3. An Independent Duty Corpsman (IDC) deployed on Republic of Singapore Navy (RSN) vessels who has been authorised by the Chief Navy Medical Officer to administer prescription-only medicines	All prescription-only medicines listed in the IDC Medications List approved by the Chief Navy Medical Officer	<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) 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	

FIFTH SCHEDULE — *continued*

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

FIFTH SCHEDULE — *continued*

<i>First column</i>	<i>Second column</i>
<i>Therapeutic product</i>	<i>Cautionary information</i>
Oxatomide	
Oxomemazine	
Phenindamine	
Pheniramine	
Phenyltoloxamine	
Promethazine	
Pyrathiazine	
Pyrrobutamine	
Thenalidine	
Thenylidamine	
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.*

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