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HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS (THERAPEUTIC PRODUCTS) REGULATIONS 2016

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EXCEPTIONS — SUPPLY OF THERAPEUTIC PRODUCTS WITHOUT REGISTRATION

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", "nursing home 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 811/2023 wef 18/12/2023]

"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;

[*Deleted by S 811/2023 wef 18/12/2023*]

[*Deleted by S 811/2023 wef 18/12/2023*]

"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", in relation to a healthcare service licensee providing a licensable healthcare service, means any individual employed or engaged by the healthcare service licensee to assist the licensee in providing a licensable healthcare service;

[S 811/2023 wef 18/12/2023]

"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;

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(*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

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(*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;

(*ga*) a nursing home service;

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(*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

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(*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;

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(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 specified healthcare service licensee pursuant to a valid prescription given by a qualified practitioner (who is a personnel of the specified healthcare service licensee) 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;

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(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;

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(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.

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(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 healthcare service licensee to a patient of the healthcare service licensee, and is in accordance with the written instructions of a qualified practitioner or collaborative prescribing practitioner who is a personnel of the healthcare service licensee;

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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

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(*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 healthcare service licensee to a patient of the healthcare service licensee, and is in accordance with the written instructions of a qualified practitioner or collaborative prescribing practitioner who is a personnel of the healthcare service licensee; 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.

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Supply of general sale list medicine by retail sale vending machine

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

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

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

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

(*d*) the package size of the medicine is the same as the package size specified for the registration of the medicine, and the

total amount of the medicine in each package does not exceed a total dosage of 3 months per individual.

Division 3 — Other requirements for supply of therapeutic products

Records of supply of prescribed therapeutic products

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

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

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

(*a*) the date of supply;

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

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

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

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

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

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

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

Supply by dispensing therapeutic products

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

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

(*b*) where the product is supplied or dispensed —

(i) at a licensed retail pharmacy — the name, address and any identification number or logo of the licensed retail pharmacy;

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(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;

(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;

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(*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

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(*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 —

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

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

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

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

(i) the therapeutic product; or

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

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

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

manner, which is likely to be understood as referring to the therapeutic product.

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

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

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

Information to be provided with therapeutic products

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

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

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

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

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

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

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

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

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

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

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

(*b*) must be legible and indelible.

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

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

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

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

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

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

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

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

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

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

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

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

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

PART 5

REGISTRATION OF THERAPEUTIC PRODUCTS

Requirements for registration

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

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

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

Whether therapeutic product subject to patent

23.—(1) In dealing with an application for the registration of a therapeutic product, the Authority must consider the following:

(*a*) whether any of the following patents under the Patents Act 1994 is in force in respect of the therapeutic product as described in the application for registration:

(i) a patent containing a claim for an active ingredient of that therapeutic product;

(ii) a patent containing a claim for a formulation or composition of that therapeutic product;

(iii) a patent containing a claim for the use of an active ingredient in the manufacture of that therapeutic product for a specific therapeutic, preventive, palliative or diagnostic use;

(*b*) if one or more patents mentioned in sub-paragraph (*a*) are in force in respect of the therapeutic product as described in the application for registration —

(i) whether the applicant for the registration of the therapeutic product is the proprietor of the patent or those patents; and

(ii) if the applicant is not the proprietor of the patent or any of the patents —

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

(B) whether the patent or any of the patents 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 one or more patents under the Patents Act 1994 mentioned in paragraph (1)(*a*) are in force in respect of the therapeutic product; and

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

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(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 mentioned in paragraph (1)(*a*) 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 a court for —

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

(ii) a declaration that the patent is valid and 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*) furnish the following to the Authority:

(i) a written notice stating that an application under sub-paragraph (*a*) has been made;

(ii) evidence of the application made under sub-paragraph (*a*);

(iii) a declaration by the proprietor in the form specified on the Authority's website that the application made under sub-paragraph (*a*) relates to a patent mentioned in paragraph (1)(*a*) that is in force in respect of the therapeutic product that is the subject of an application for registration.

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(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.

(11) To avoid doubt, this regulation does not apply to the following patents:

(*a*) a process patent, other than a process patent that contains a claim for the use of an active ingredient in the manufacture of a therapeutic product for a specific therapeutic, preventive, palliative or diagnostic use;

(*b*) a patent that contains only claims relating to packaging;

(*c*) a patent that contains only claims relating to metabolites;

(*d*) a patent that contains only claims relating to intermediates.

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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 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.

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Offences for making false declaration

25. A person who, when making a declaration under regulation 23(2) or (8)(*b*)(iii) —

(*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.

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Protection of confidential supporting information relating to innovative therapeutic product applications

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

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

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

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

"confidential information" includes —

(*a*) trade secrets; and

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

"confidential supporting information" means confidential information given —

(*a*) in, or in relation to, an innovative therapeutic product application; and

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

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

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

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

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

Circumstances where protection under regulation 26 does not apply

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

(*a*) disclose that confidential supporting information, or use that confidential supporting information for the purpose of determining whether to grant any other application to register a therapeutic product —

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

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

(*b*) disclose that confidential supporting information to a Government department or statutory body for the purpose of facilitating or assisting such Government department or statutory body in carrying out its duties if,

in the opinion of the Authority, the Government department or statutory body, as the case may be, will take reasonable steps to ensure the confidential supporting information is kept confidential; or

(*c*) disclose that confidential supporting information to, if so requested by, any one or more of the following:

(i) the World Health Organization;

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

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

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

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

(*a*) that applicant —

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

(ii) has not notified the Authority in writing that *P*'s authority to grant that consent has been withdrawn; or

(*b*) that applicant's rights in respect of the relevant confidential supporting information have been transferred to *P* and the applicant or *P* has notified the Authority in writing of the transfer.

Disclosure of information on applications for registration

28. For the purposes of section 66(2)(*d*) of the Act, the Authority may from time to time disclose, for the information of the public and in the manner determined by the Authority, such particulars of applications for the registration of therapeutic products which it

receives as it may determine, provided that the particulars to be disclosed under this regulation exclude —

(*a*) any trade secret; and

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

Registration exclusivity

29. Where —

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

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

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

PART 6

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

Division 1 — General duties

Duty to comply with enforcement requirements

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

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

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

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

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

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

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

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

Duty to maintain records of manufacture

31.—(1) A manufacturer of a therapeutic product, other than a healthcare 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)(*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 — Specified healthcare service licensees

[S 811/2023 wef 18/12/2023]

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

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

46.—(1) 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) [*Deleted by S 811/2023 wef 18/12/2023*]

(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*) [*Deleted by S 811/2023 wef 18/12/2023*]

(*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*) [*Deleted by S 811/2023 wef 18/12/2023*]

(*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 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 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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[S 811/2023 wef 18/12/2023]

[S 811/2023 wef 18/12/2023]

Transfer of therapeutic products by specified healthcare service licensees without wholesaler's licence

47.—(1) [*Deleted by S 811/2023 wef 18/12/2023*]

(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*) [*Deleted by S 811/2023 wef 18/12/2023*]

(*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*) [*Deleted by S 811/2023 wef 18/12/2023*]

(*b*) any approved permanent premises of B;

(*c*) any approved permanent premises of another specified healthcare service licensee.

(4) 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 specified healthcare service licensee without holding a wholesaler's licence.

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

[S 811/2023 wef 18/12/2023]

[S 811/2023 wef 18/12/2023]

Division 2 — Licensed retail pharmacies

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

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

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

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

(*c*) the compounding is carried out —

(i) at the licensed retail pharmacy;

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

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

(iv) in the case of a sterile therapeutic product, at premises where standards established for the operation of clean rooms and the preparation of 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 specified healthcare service licensee.

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[S 811/2023 wef 18/12/2023]

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

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

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

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

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

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

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

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

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

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

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

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

(*a*) is to a 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 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 specified healthcare service licensee; and

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(*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*) [*Deleted by S 811/2023 wef 18/12/2023*]

(*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) [*Deleted by S 811/2023 wef 18/12/2023*]

(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 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 specified healthcare service licensee;

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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) [*Deleted by S 811/2023 wef 18/12/2023*]

(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 specified healthcare service licensee in accordance with the requirements in regulation 5(1)(*b*)(i);

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(*g*) the supply by 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 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.

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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) [*Deleted by S 811/2023 wef 18/12/2023*]

(ii) a specified healthcare service licensee for the use of a patient of the specified healthcare service licensee;

(*b*) [*Deleted by S 811/2023 wef 18/12/2023*]

(*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 specified healthcare service licensee mentioned in paragraph (1)(*a*)(ii) or (*c*);

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(*b*) in accordance with the chemical composition and the written instructions of a qualified practitioner who is a personnel of —

(i) [*Deleted by S 811/2023 wef 18/12/2023*]

(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 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 repacking for the purpose of dispensing the therapeutic product.

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[S 811/2023 wef 18/12/2023]

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;

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"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:

Allobarbital

Alprazolam

Amineptine

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

Aminorex

Amobarbital

Barbital

Bromazepam

Brotizolam

Butalbital

Butobarbital

Camazepam

Cathine

Chlordiazepoxide

Clobazam

Clonazepam

Clonazolam

Clorazepate

Clotiazepam

FIRST SCHEDULE — *continued*

Cloxazolam

Cyclobarbital

Delorazepam

Diazepam

Diclazepam

Estazolam

Ethchlorvynol

Ethinamate

Ethyl loflazepate

Etilamfetamine

Etizolam

Fencamfamin

Fenproporex

Flualprazolam

Flubromazolam

Fludiazepam

Flurazepam

Glutethimide

Halazepam

Haloxazolam

Ketazolam

Lefetamine

Loprazolam

Lorazepam

Lormetazepam

Mazindol

Medazepam

Mefenorex

Meprobamate

FIRST SCHEDULE — *continued*

Mesocarb

Methylphenobarbital

Methyprylon

Midazolam

Nitrazepam

Nordazepam

Oxazepam

Oxazolam

Pemoline

Pentazocine

Pentobarbital

Phenazepam

Phenobarbital

Phentermine

Pinazepam

Prazepam

Secbutabarbital

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

Aceclofenac

Acemetacin

Acepromazine

Acetanilide

Acetazolamide

Acetohexamide

Acetorphine

Acetylcarbromal

Acetylcysteine

Acetyldigoxin

SECOND SCHEDULE — *continued*

Acetyldihydrocodeine

Acetylmethadol

Acetylstrophanthidin

Acipimox

Acitretin

Aclidinium

Acrivastine

Actinomycins

Acyclovir

Adalimumab

Adapalene

Adefovir

Adicillin

Adiphenine

Adrenaline

Adrenocorticotropic hormone (ACTH)

Afatinib

Aflibercept

Agalsidase alfa

Agalsidase beta

Agomelatine

Alatrofloxacin

Albutrepenonacog alfa

Alcaftadine

Alclofenac

Alclometasone

Alcuronium

Aldesleukin

Aldosterone

SECOND SCHEDULE — *continued*

Alectinib

Alefacept

Alemtuzumab

Alendronic acid

Alfacalcidol

Alfentanil

Alfuzosin

Algestone

Alglucosidase alfa

Alirocumab

Aliskiren

Allobarbitone

Allopurinol

Allylisopropylacetylurea

Allyloestrenol

Allylprodine

Alminoprofen

Almitrine

Alogliptin

Alosetron

Alpelisib

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

Alphacetylmethadol

Alphachloralose

Alphadolone

Alphameprodine

Alphamethadol

Alphaprodine

Alphaxalone

SECOND SCHEDULE — *continued*

Alprazolam

Alprenolol

Alprostadil

Alseroxylon

Alteplase

Altretamine

Amantadine

Ambenonium

Ambrisentan

Ambroxol

Ambuside

Ambutonium

Ametazole

Amethocaine

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

Amidopyrine

Amifostine

Amikacin

Amiloride

Amineptine

Aminocaproic acid

Aminoglutethimide

Aminolevulinic acid

Aminophylline

Aminopterin

Aminorex

Amiodarone

Amisulpride

Amitriptyline

SECOND SCHEDULE — *continued*

Amivantamab

Amlodipine

Ammonium lactate

Amoxycillin

Amphetamine

Amphomycin

Amphotericin B

Ampicillin

Amprenavir

Amrinone

Amsacrine (M-AMSA)

Amylobarbitone

Amylocaine

Anagrelide

Anastrozole

Ancrod

Androsterone

Angiotensin amide

Anidulafungin

Anileridine

Anistreplase

Antazoline

Apalutamide

Apixaban

Apomorphine

Apraclonidine

Apramycin

Apremilast

Aprepitant

SECOND SCHEDULE — *continued*

Aprobarbitone

Aprotinin

Aripiprazole

Arotinolol

Arsenic trioxide

Arsphenamine

Arteether

Artemether

Artemisinin

Artesunate

Articaine

Asciminib

Asenapine

Aspoxicillin

Astemizole

Asunaprevir

Atazanavir

Atenolol

Atezolizumab

Atomoxetine

Atorvastatin

Atosiban

Atovaquone

Atracurium

Atropine

Auranofin

Avanafil

Avelumab

Avibactam

SECOND SCHEDULE — *continued*

Axitinib

Azacitidine

Azacyclonol

Azaperone

Azapropazone

Azasetron

Azatadine

Azathioprine

Azelaic acid

Azelastine

Azidamphenicol

Azidocillin

Azilsartan

Azithromycin

Aztreonam

Bacampicillin

Bacitracin

Baclofen

Baloxavir marboxil

Bambermycin

Bamipine

Barbitone

Barbituric acid

Baricitinib

Basiliximab

Becaplermin

Beclamide

Beclomethasone

Befunolol

SECOND SCHEDULE — *continued*

Bekanamycin

Belantamab mafodotin

Belimumab

Bemegride

Benactyzine

Benapryzine

Benazepril

Bendamustine

Bendrofluazide

Benethamine penicillin

Benfluorex

Benoxaprofen

Benperidol

Benralizumab

Benserazide

Benzamidosalicylic acid

Benzathine penicillin

Benzbromarone

Benzethidine

Benzhexol

Benzilonium

Benzocaine

Benzoctamine

Benzoestrol

Benzphetamine

Benzquinamide

Benzthiazide

Benztropine

Benzylfentanyl

SECOND SCHEDULE — *continued*

Benzylmorphine

Benzylpenicillin

Besifloxacin

Betahistine

Betameprodine

Betamethadol

Betamethasone

Betaprodine

Betaxolol

Bethanechol

Bethanidine

Betiatide

Bevacizumab

Bevonium

Bezafibrate

Bezitramide

Bicalutamide

Bicisate

Bictegravir

Bifonazole

Bilastine

Bimatoprost

Biperiden

Bisoprolol

Bleomycin

Blinatumomab

Boceprevir

Boldenone undecenoate

Bopindolol

SECOND SCHEDULE — *continued*

Bortezomib

Bosentan

Botulinum toxin

Brentuximab

Bretylium

Brexipiprazole

Brigatinib

Brimonidine

Brinzolamide

Brolamfetamine

Bromazepam

Bromhexine

Bromocriptine

Bromodiphenhydramine

Bromvaletone

Brotizolam

Budesonide

Bufexamac

Buflomedil

Buformin

Bumadizone calcium

Bumetanide

Bunazosin

Buphenine

Bupivacaine

Bupranolol

Buprenorphine

Bupropion

Burosumab

SECOND SCHEDULE — *continued*

Buserelin

Buspirone

Busulphan

Butacaine

Butalbital

Butamirate

Butanilicaine

Butizide

Butobarbitone

Butoconazole

Butriptyline

Butropium

Butylchloral hydrate

Cabazitaxel

Cabergoline

Cabimicina

Cabotegravir

Cabozantinib

Calcipotriol

Calcitonin

Calcitriol

Calcium barbiturate

Calcium carbimide

Calcium dobesilate

Calfactant

Camazepam

Canagliflozin

Canakinumab

Candesartan

SECOND SCHEDULE — *continued*

Candicidin

Capecitabine

Capmatinib

Capreomycin

Captodiame

Captopril

Caramiphen

Carbachol

Carbamazepine

Carbenicillin

Carbenoxolone

Carbetocin

Carbidopa

Carbimazole

Carboplatin

Carboprost

Carbromal

Carbutamide

Carfecillin

Carfentanil

Carfilzomib

Cariprazine

Carisoprodol

Carmustine

Carperidine

Carprofen

Carteolol

Carvedilol

Caspofungin

SECOND SCHEDULE — *continued*

Cathine

Cathinone

Cefaclor

Cefadroxil

Cefamandole

Cefatrizine

Cefdinir

Cefepime

Cefixime

Cefodizime

Cefoperazone

Cefotaxime

Cefotiam

Cefoxitin

Cefpirome

Cefprozil

Cefsulodin

Ceftaroline

Ceftazidime

Ceftibuten

Ceftizoxime

Ceftolozane

Ceftriaxone

Cefuroxime

Celecoxib

Cephalexin

Cephaloglycin

Cephaloram

Cephaloridine

SECOND SCHEDULE — *continued*

Cephalothin

Cephazolin

Cephradine

Ceritinib

Cerivastatin

Certolizumab

Cetrorelix

Cetuximab

Chenodeoxycholic acid

Chloral hydrate

Chlorambucil

Chloramphenicol

Chlorcyclizine

Chlordiazepoxide

Chlormadinone

Chlormerodrin

Chlormethiazole

Chlormezanone

Chlormidazole

Chlorothiazide

Chloroquine

Chlorpheniramine

Chlorphenoxamine

Chlorphentermine

Chlorpromazine

Chlorpropamide

Chlorprothixene and other derivatives of 9-methylenethiazanthene

Chlorquinaldol

Chlortetracycline

SECOND SCHEDULE — *continued*

Chlorthalidone and other derivatives of o-chlorobenzene sulphonamide

Chlorzoxazone

Cholestyramine

Choline Theophyllinate

Chorionic gonadotrophin

Chromium [51CR]

Chromomycin A

Ciclacillin

Ciclesonide

Ciclopirox

Cilastatin

Cilazapril

Cilostazol

Cimetidine

Cinacalcet

Cinchocaine

Ciprofibrate

Ciprofloxacin

Cisapride

Cisatracurium

Cisplatin

Citalopram

Citicoline

Cladribine

Clarithromycin

Clavulanic acid

Clebopride

Clemastine

Clemizole

SECOND SCHEDULE — *continued*

Clenbuterol

Clidinium

Clindamycin

Clioquinol

Clobazam

Clobenzorex

Clobetasol

Clobetasone

Clobutinol

Clodronic acid

Clofarabine

Clofazimine

Clofedanol

Clofibrate

Clomiphene

Clomipramine

Clomocycline

Clonazepam

Clonazolam

Clonidine

Clonitazene

Clopamide

Clopenthixol

Clopidogrel

Cloprostenol

Clorazepate

Clorexolone

Clorprenaline

Clostebol

SECOND SCHEDULE — *continued*

Clostridiopeptidase A

Clotiazepam

Clotrimazole

Cloxacillin

Cloxacillin benzathine

Cloxazolam

Cloxiquine

Clozapine

Cobicistat

Cobimetinib

Codeine

Co-dergocrine mesylate

Colchicine

Colestipol

Colimycin

Colistin

Corifollitropin alfa

Corticorelin

Cortisone

Crisaborole

Crisantaspase

Crizotinib

Cropropamide

Crotethamide

Cyclandelate

Cyclarbamate

Cyclizine

Cyclobarbitone

Cyclofenil

SECOND SCHEDULE — *continued*

Cyclopenthiazide

Cyclopentolate

Cyclophosphamide

Cycloserine

Cyclosporin

Cyclothiazide

Cycrimine

Cyproheptadine

Cyproterone

Cytarabine

Dabigatran

Dabrafenib

Dacarbazine

Daclatasvir

Daclizumab

Dacomitinib

Dactinomycin

Dalfopristin

Dalteparin

Danazol

Danthron

Dantrolene

Dapagliflozin

Dapoxetine

Dapsone

Daptomycin

Daratumumab

Darbepoetin alfa

Darolutamide

SECOND SCHEDULE — *continued*

Darunavir

Dasabuvir

Dasatinib

Daunorubicin

Davesomeran

Debrisoquine

Deferasirox

Deferiprone

Deferoxamine

Degarelix

Dehydroemetine

Dehydroepiandrosterone (DHEA)

Delapril

Delmadinone

Delorazepam

Demecarium

Demeclocycline

Demoxytocin

Denosumab

Deoxycholic acid

Deoxycortone

Deptropine

Deserpidine

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

Desfluorotriamcinolone

Desflurane

Desipramine

Deslanoside

Desloratadine

SECOND SCHEDULE — *continued*

Desmopressin

Desogestrel

Desomorphine

Desonide

Desoxymethasone

Desvenlafaxine

Dexamethasone

Dexamphetamine

Dexetimide

Dexfenfluramine

Dexketoprofen

Dexlansoprazole

Dexmedetomidine

Dexrazoxane

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

Dextromoramide

Dextropropoxyphene

Dextrorphan

Dextrothyroxine

Diacetylmorphine

Diacetylnalorphine

Diamorphine

Diampromide

Diazepam

Diazoxide

Dibekacin

Dibenzepin

Dibucaine

Dichloralphenazone

SECOND SCHEDULE — *continued*

Dichlorophenarsine

Dichlorphenamide

Diclazepam

Diclofenac

Dicloxacillin

Didanosine

Dienoestrol

Dienogest

[*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

SECOND SCHEDULE — *continued*

Dimethindene

Dimethisoquin

Dimethisterone

Dimethothiazine

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

SECOND SCHEDULE — *continued*

Dithienylallylamines

Dobutamine

Docetaxel

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

SECOND SCHEDULE — *continued*

Dutasteride

Dydrogesterone

Dyflos

Ebastine

Econazole

Ecothiopate

Ectylurea

Eculizumab

Edoxaban

Edoxudine

Edrophonium

Efalizumab

Efavirenz

Elasomeran

Elbasvir

Eletriptan

Eltrombopag

Elvitegravir

Embramine

Embutramide

Emedastine

Emepronium

Emicizumab

Empagliflozin

Emtricitabine

Emylcamate

Enalapril

Enalaprilat

Encainide

SECOND SCHEDULE — *continued*

Enflurane

Enfortumab vedotin

Enfuvirtide

Enoxaparin

Entacapone

Entecavir

Entrectinib

Enzalutamide

Eperisone

Ephedrine

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

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

Ethisterone

SECOND SCHEDULE — *continued*

Ethoglucid

Ethoheptazine

Ethopropazine

Ethosuximide

Ethotoin

Ethyl biscoumacetate

Ethyl loflazepate

Ethyl p-piperidinoacetylaminobenzoate

Ethylacetanilide

Ethylmorphine

Ethylnoradrenaline

Ethyloestrenol

Ethylstibamine

Ethynodiol

Etidronic acid

Etilamfetamine

Etizolam

Etodolac

Etofenamate

Etofibrate

Etofylline

Etomidate

Etonitazene

Etonogestrel

Etoposide

Etoricoxib

Etorphine

Etoxeridine

Etravirine

SECOND SCHEDULE — *continued*

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

Fenpipramide

Fenpiprane

SECOND SCHEDULE — *continued*

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

Fludiazepam

Fludrocortisone

Flufenamic acid

SECOND SCHEDULE — *continued*

Flugestone

Flumazenil

Flumedroxone

Flumethasone

Flumethiazide

Flunisolide

Flunitrazepam

Fluocinolone

Fluocinonide

Fluocortolone

Fluopromazine

Fluoro-2-deoxy-d-glucose

Fluoroacetamide

Fluoroacetanilide

Fluorometholone

Fluorouracil

Fluothane

Fluoxetine

Fluoxymesterone

Flupenthixol

Fluperolone

Fluphenazine

Fluprednidene

Fluprednisolone

Fluprostenol

Flurandrenolone

Flurazepam

Flurbiprofen

Fluspirilene

SECOND SCHEDULE — *continued*

Flutamide

Flutemetamol

Fluticasone

Fluvastatin

Fluvoxamine

Follicle stimulating hormone (FSH)

Follitropin alfa

Follitropin delta

Fondaparinux

Formestane

Formosulphathiazole

Formoterol

Fosamprenavir

Fosaprepitant

Foscarnet

Fosfestrol

Fosfomycin

Fosinopril

Fotemustine

Framycetin

Fremanezumab

Frusemide

Ftorafur

Fulvestrant

Fumagillin

Furaltadone

Furazolidone

Furethidine

Fusafungine

SECOND SCHEDULE — *continued*

Fusidic acid

Gabapentin

Gadobenic acid

Gadobutrol

Gadodiamide

Gadopentetic acid

Gadoteric acid

Gadoversetamide

[*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

Gestodene

Gestrinone

Gestronol

Gilteritinib

Gimeracil

Glafenine

SECOND SCHEDULE — *continued*

Glecaprevir
Glibenclamide
Glibornuride
Gliclazide
Glimepiride
Glipizide
Gliquidone
Glucagon
Glutethimide
Glyceryl trinitrate
Glycopyrrolate
Glycopyrronium
Glymidine
Golimumab
Gonadorelin
Goserelin
Gramicidins
Granisetron
Grazoprevir
Grepafloxacin
Griseofulvin
Guanethidine
Guanoclor
Guanoxan
Guselkumab
Hachimycin
Halazepam
Halcinonide
Halofantrine

SECOND SCHEDULE — *continued*

Halometasone

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

Haloprogin

Halothane

Haloxazolam

Heparin

Heparin calcium

Heptabarbitone

Heptaminol

Hexamethonium

Hexamethylmelamine

Hexapropymate

Hexobarbitone

Hexoestrol

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

Histrelin acetate

Homatropine

Homochlorcyclizine

Hydralazine

Hydrochlorothiazide

Hydrocodone

Hydrocortisone

Hydromorphinol

Hydromorphone

Hydroquinone

Hydroxychloroquine

Hydroxycinchoninic

Hydroxyprogesterone

SECOND SCHEDULE — *continued*

Hydroxyquinoline

Hydroxyurea

Hydroxyzine

Hygromycin B

Hyoscine

Ibacitabine

Ibandronic acid

Ibrutinib

Ibuprofen

Idarubicin

Idarucizumab

Idelalisib

Idoxuridine

Idrocilamide

Idursulfase

Ifenprodil

Ifosfamide

Iloprost

Imatinib

Imidapril

Imiglucerase

Imipenem

Imipramine

Imiquimod

Inclisiran

Indacaterol

Indapamide

Indinavir

Indium pentetreotide

SECOND SCHEDULE — *continued*

Indobufen

Indomethacin

Infliximab

Inotuzumab ozogamicin

Interferons

Iodixanol

Iodine-131

Ioflupane

Ipilimumab

Ipratropium

Iprindole

Iproniazid

Irbesartan

Irinotecan

Isatuximab

Isavuconazonium

Isepamicin

Isoaminile

Isocarboxazid

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

Isoetharine

Isoflurane

Isomethadone (isoamidone)

Isoniazid

Isoprenaline

Isopropamide

Isopyrin

Isosorbide

Isothipendyl

SECOND SCHEDULE — *continued*

Isotretinoin

Isoxicam

Isoxsuprine

Isradipine

Itopride

Itraconazole

Ivabradine

Ivermectin

Ixabepilone

Ixazomib

Ixekizumab

Kanamycin

Kanendomycin

Ketamine

Ketanserin

Ketazolam

Ketobemidone

Ketoconazole

Ketoprofen

Ketorolac

Ketotifen

Labetalol

Lacidipine

Lacosamide

Lafutidine

Lamivudine

Lamotrigine

Lanreotide

Lansoprazole

SECOND SCHEDULE — *continued*

Lanthanum carbonate

Lapatinib

Laronidase

Laropiprant

Larotrectinib

L-Asparaginase

Latanoprost

Latanoprostene

Laudexium

Ledipasvir

Lefetamine

Leflunomide

Lemborexant

Lenalidomide

Lenograstim

Lenvatinib

Lepirudin

Lercanidipine

Letermovir

Letrozole

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

Leuprorelin

Levamisole

Levamphetamine

Levetiracetam

Levobunolol

Levocabastine

Levocetirizine

Levodopa

SECOND SCHEDULE — *continued*

Levofloxacin

Levomethamphetamine

Levomethorphan

Levomoramide

Levonorgestrel

Levorphanol

Levosimendan

Levothyroxine

Lidoflazine

Lignocaine

Linagliptin

Lincomycin

Linezolid

Lipegfilgrastim

Liothyronine

Liraglutide

Lisdexamfetamine

Lisinopril

Lisuride

Lithium carbonate

Lixisenatide

Lodoxamide

Lofentanil

Lofepramine

Lomefloxacin

Lomustine

Lonazolac

Lonoccog alfa

Lopinavir

SECOND SCHEDULE — *continued*

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

Lutropin alfa

Lymecycline

Lynoestrenol

Lypressin

Lysuride

Macitentan

Mafenide

Mangafodipir

Mannitol hexanitrate

Mannomustine

Maprotiline

SECOND SCHEDULE — *continued*

Maraviroc

Mavacamten

Mazindol

Mebanazine

Mebezonium

Mebhydrolin

Mebutamate

Mecamylamine

Meclastine

Meclofenamic acid

Meclofenoxate

Mecloqualone

Meclozine

Medazepam

Medigoxin

Medrogestone

Medroxyprogesterone

Mefenamic acid

Mefenorex

Mefloquine

Mefruside

Megestrol

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

Melengestrol

Melitracen

Meloxicam

Melphalan

Memantine

Menotrophin

SECOND SCHEDULE — *continued*

Mepenzolate

Mephenesin

Mephentermine

Mepivacaine

Mepolizumab

Meprobamate

Mepyramine

Mequitazine

Mercaptopurine

Meropenem

Mesalazine

MESNA (2-mercaptoethane sulfonate sodium)

Mesocarb

Mesoridazine

Mestanolone

Mesterolone

Mestranol

Metabutethamine

Metaiodobenzylguanidine (I-131)

Metaraminol

Metaxalone

Metazocine

Metergoline

Metformin

Methacycline

Methadone

Methadyl acetate

Methallenoestril

Methandienone

SECOND SCHEDULE — *continued*

Methandriol

Methantheline

Methapyrilene

Methaqualone

Metharbitone

Methdilazine

Methenolone

Methicillin

Methimazole

Methisoprinol

Methixene

Methocarbamol

Methohexitone

Methoin

Methoserpidine

Methotrexate

Methotrimeprazine

Methoxamine

Methoxsalen

Methoxyflurane

Methoxyphenamine

Methsuximide

Methyclothiazide

Methyl aminolevulinate

Methylaminoheptane

Methylamphetamine

Methyldihydromorphine

Methyldopa

Methyldopate

SECOND SCHEDULE — *continued*

Methylephedrine

Methylergometrine

Methylnaltrexone

Methylpentynol

Methylphenidate

Methylphenobarbitone

Methylprednisolone

Methylsulphonal

Methyltestosterone

Methylthioninium

Methylthiouracil

Methyprylone

Methysergide

Metipranolol

Metoclopramide

Metolazone

Metomidate

Metopon

Metoprolol

Metronidazole

Mexiletine

Mianserin

Mibefradil

Micafungin

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

Micronomicin

Midazolam

Midecamycin

Midodrine

SECOND SCHEDULE — *continued*

Midostaurin

Mifepristone

Miglitol

Milrinone

Miltefosine

Minaprine

Minocycline

Minoxidil (other than topical preparations)

Mirabegron

Mirtazapine

Misoprostol

Mithramycin

Mitobronitol

Mitomycins

Mitopodozide

Mitotane

Mitoxantrone

Mivacurium

Mizolastine

m-Nitrophenol; o-Nitrophenol; p-Nitrophenol

Moclobemide

Moexipril

Molgramostim

Molindone

Mometasone

Monofluoroacetic acid

Montelukast

Morazone

Morinamide

SECOND SCHEDULE — *continued*

Moroctocog alfa

Moroxydine

Morphine

Moxalactam

Moxifloxacin

Moxonidine

Mupirocin

Muromonab-CD3

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

Mycophenolic acid

Myrophine

Myrtecaine

Nabumetone

N-Acetylaspartyl glutamic acid; spaglumic acid

Nadolol

Nadroparin

Nafarelin

Nafcillin

Naftidrofuryl

Naftifine

Nalbuphine

Nalidixic acid

Nalmefene

Nalorphine

Naloxone

Naltrexone

Nandrolone

Naproxen

Naratriptan

SECOND SCHEDULE — *continued*

Natalizumab

Natamycin

Nateglinide

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

Nealbarbitone

Nebivolol

Necitumumab

Nedocromil

Nefazodone

Nefopam

Nelfinavir

Neoarsphenamine

Neomycin

Neostigmine

Nepafenac

Neratinib

Netarsudil

Netilmicin

Netupitant

Nevirapine

Nialamide

Niaprazine

Nicardipine

Nicergoline

Nicocodine

Nicodicodine

Nicomorphine

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

Nicoumalone

SECOND SCHEDULE — *continued*

Nifedipine

Nifuroxazide

Nifurzide

Nikethamide

Nilotinib

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

SECOND SCHEDULE — *continued*

Noradrenaline

Noramidopyrine

Norbuprenorphine

Norcodeine

Nordazepam

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

SECOND SCHEDULE — *continued*

Oestrone

Ofatumumab

Ofloxacin

Olanzapine

Olaparib

Oleandomycin

Olmesartan

Olodaterol

Olopatadine

Olsalazine

Omalizumab

Ombitasvir

Omeprazole

Omidenepag

Ondansetron

Opipramol

Orciprenaline

Orelabrutinib

Orlistat

Ornidazole

Orphenadrine

Orthocaine

Oseltamivir

Osimertinib

Ospemifene

Oteracil

Oxaliplatin

Oxamniquine

Oxandrolone

SECOND SCHEDULE — *continued*

Oxantel

Oxatomide

Oxazepam

Oxazolam

Oxcarbazepine

Oxedrine

Oxidronic acid

Oxiracetam

Oxolinic acid

Oxomemazine

Oxophenarsine

Oxpentifylline

Oxprenolol

Oxybuprocaine

Oxybutynin

Oxycodone

Oxymesterone

Oxymetazoline

Oxymetholone

Oxymorphone

Oxypertine

Oxyphenbutazone

Oxyphencyclimine

Oxyphenonium

Oxytetracycline

Oxytocin

Ozanimod

p-Aminobenzoic acid

Paclitaxel

SECOND SCHEDULE — *continued*

Palbociclib

Paliperidone

Palivizumab

Palonosetron

Pamidronate

[*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

SECOND SCHEDULE — *continued*

Pemafibrate

Pembrolizumab

Pemetrexed

Pemoline

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

SECOND SCHEDULE — *continued*

Pethidine

Pethidinic acid

Phenacaine

Phenacemide

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

SECOND SCHEDULE — *continued*

Phensuximide

Phentermine

Phentolamine

Phenylbutazone

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

SECOND SCHEDULE — *continued*

Pirfenidone

Piribedil

Piritramide

Piroxicam

Pirprofen

Pitavastatin

Pivmecillinam

Pizotifen

Plerixafor

Polatuzumab vedotin

Poldine

Polidexide

Polymethylene-bistrimethylammonium salts

Polymyxins

Polyoestradiol

Polythiazide

Pomalidomide

Ponatinib

Posaconazole

Practolol

Pralatrexate

Pralidoxime

Pralsetinib

Pramipexole

Prasugrel

Pravastatin

Prazepam

Praziquantel

Prazosin

SECOND SCHEDULE — *continued*

Prednicarbate

Prednisolone

Prednisone

Pregabalin

Prenoxdiazine

Prenylamine

Prilocaine

Procaine

Primaquine

Primidone

Prindolol

Probenecid

Probucol

Procainamide

Procaine penicillin

Procarbazine

Prochlorperazine

Procyclidine

Profenone

Progesterone

Proguanil

Prolintane

Promazine

Promestriene

Promethazine

Promoxolane

Pronethalol

Propafenone

Propanidid

SECOND SCHEDULE — *continued*

Propantheline

Proparacaine

Propicillin

Propiomazine

Propiram

Propiverine

Propofol

Propoxyphene

Propranolol

Propylhexedrine

Propylthiouracil

Propyromazine

Proquamezine

Proquazone

Prostaglandins

Protamine

Prothionamide

Prothipendyl

Protirelin

Protriptyline

Proxymetacaine

Proxyphylline

Prucalopride

Pyrathiazine

Pyrazinamide

Pyridinolcarbamate

Pyridostigmine

Pyrimethamine

Pyritinol

SECOND SCHEDULE — *continued*

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

SECOND SCHEDULE — *continued*

Raubasine

Raxtozinameran

Razoxane

Reboxetine

Regorafenib

Remdesivir

Remifentanil

Repaglinide

Reserpine

Retapamulin

Reteplase

Retigabine

Retinoic acid

Revefenacin

Reviparin

Rhodamine B

Ribavirin

Ribociclib

Rifamide

Rifampicin

Rifapentine

Rifaximin

Rilmenidine

Rilpivirine

Riluzole

Rimegepant

Rimexolone

Rimiterol

Riociguat

SECOND SCHEDULE — *continued*

Ripasudil

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

SECOND SCHEDULE — *continued*

Ruxolitinib

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

SECOND SCHEDULE — *continued*

Siltuximab

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 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

Streptozocin

Strontium [89Sr]

Styramate

Succinylsulphathiazole

Sucroferric oxyhydroxide

Sufentanil

Sugammadex

Sulbactam

Sulbenicillin

Sulfabenzamide

Sulfacytine

Sulfametopyrazine

Sulfametrole

Sulindac

Sulphabromomethazine

Sulphacetamide

Sulphachlorpyridazine

Sulphadiazine

SECOND SCHEDULE — *continued*

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

Sulphinpyrazone

SECOND SCHEDULE — *continued*

Sulphomyxin

Sulphonal

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

Tegafur

Tegaserod

SECOND SCHEDULE — *continued*

Tegoprazan
Teicoplanin
Telbivudine
Telithromycin
Telmisartan
Temazepam
Temozolomide
Temsirolimus
Tenecteplase
Teniposide
Tenofovir
Tenonitrozole
Tenoxicam
Tepotinib
Terazosin
Terbinafine
Terbutaline
Terconazole
Terfenadine
Teriflunomide
Teriparatide
Terlipressin
Tertatolol
Testosterone
Tetrabenazine
Tetracaine
Tetracosactide
Tetracyclines
Tetrahydrocannabinol

SECOND SCHEDULE — *continued*

Tetrazepam

Tetrofosmin

Tezepelumab

Thalidomide

Thallium

Thebacon

Thenalidine

Thenyldiamine

Theofibrate

Theophylline

Thiabendazole

Thiacetazone

Thialbarbitone

Thiamazole

Thiambutosine

Thiamphenicol

Thiazinamium

Thiethylperazine

Thiocarlide

Thioguanine

Thiopentone

Thiopropazate

Thioproperazine

Thioridazine

Thiotepa

Thiothixene

Thiouracil

Thymalfasin

Thymoxamine

SECOND SCHEDULE — *continued*

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

Thyrotrophin

Thyroxine

Tiagabine

Tianeptine

Tiapride

Tiaprofenic acid

Tibolone

Ticagrelor

Ticarcillin

Ticlopidine

Tiemonium

Tigecycline

Tigloidine

Tilidine

Tiludronic acid

Timepidium

Timolol

Tinidazole

Tinzaparin

Tioconazole

Tiotropium

Tipiracil

Tirilazad

Tirofiban

Tirzepatide

Tixocortol

Tizanidine

Tobramycin

SECOND SCHEDULE — *continued*

Tocainide

Tocilizumab

Tofacitinib

Tofenacin

Tolazamide

Tolazoline

Tolbutamide

Tolcapone

Tolmetin

Toloxatone

Tolperisone

Tolpropamine

Tolterodine

Tolvaptan

Topiramate

Topotecan

Toremifene

Tosufloxacin

Tozinameran

Trabectedin

Tramadol

Trametinib

Tranexamic acid

Tranylcypromine

Trastuzumab

Travoprost

Trazodone

Treosulphan

Tretamine

SECOND SCHEDULE — *continued*

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

Trimetaphan

Trimetazidine

Trimethoprim

Trimetrexate

Trimipramine

SECOND SCHEDULE — *continued*

Trimustine

Tripamide

Tripelennamine

Triptorelin

Tromantadine

Tropicamide

Tropisetron

Trospium

Trovafloxacin

Troxidone

Tubocurarine

Tucatinib

Turoctocog alfa

Tybamate

Tylosin

Ulipristal

Umeclidinium

Unoprostone

Upadacitinib

Uramustine

Urapidil

Urea [13C]

Urea [14C]

Ureamycin

Urethane

Urokinase

Ursodeoxycholic acid

Ustekinumab

Valaciclovir

SECOND SCHEDULE — *continued*

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

Vildagliptin

Viloxazine

Vinbarbitone

Vinblastine

Vincristine

Vindesine

SECOND SCHEDULE — *continued*

Vinflunine

Vinorelbine

Vinpocetine

Vinylbital

Viomycin

Virginiamycin

Vismodegib

Vonoprazan

Voriconazole

Vortioxetine

Voxilaprevir

Warfarin

Xamoterol

Xipamide

Xylazine

Xylometazoline

Yttrium-90

Zafirlukast

Zalcitabine

Zanamivir

Zanubrutinib

Zidovudine

Zipeprol

Ziprasidone

Zofenopril

Zolendronic acid

Zolmitriptan

Zolpidem

Zopiclone

SECOND SCHEDULE — *continued*

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

Amyl nitrite

Bambuterol

Benzydamine

Brompheniramine

Buclizine

Butyl aminobenzoate

Carbinoxamine

SECOND SCHEDULE — *continued*

Carbocysteine

Cetirizine

Cinnarizine

Dexchlorpheniramine

Dextromethorphan

Dicycloverine

Diphenhydramine

Diphenoxylate

Flunarizine

Isoconazole

Levodropropizine

Loperamide

Loratadine

Mebendazole

Mebeverine

Miconazole

Naphazoline

Nicotine

Oxethazaine

Parachlorophenol

Phenyltoloxamine

Pholcodine

Podophyllum resin

Podophyllotoxin

Policresulen

Procaterol

Pseudoephedrine

Sodium cromoglycate

Tetrahydrozoline

SECOND SCHEDULE — *continued*

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*)

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

First column	*Second column*	*Third column*
Class of persons	*Type of prescription-only medicine*	*Conditions*
Singapore Navy (RSN) vessels who has been authorised by the Chief Navy Medical Officer to administer prescription-only medicines	approved by the Chief Navy Medical Officer	any person other than personnel on board RSN vessels when the vessels are out at sea, or on military operations and exercises; (*b*) must carry out the administration of the prescription-only medicines in accordance with IDC clinical protocols approved by the Chief Navy Medical Officer; and (*c*) must keep proper records of the IDC's administration of the prescription-only medicines

FOURTH SCHEDULE

Regulation 20(2)

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

FIFTH SCHEDULE

Regulation 20(3)

CAUTIONARY INFORMATION TO BE LABELLED ON THERAPEUTIC PRODUCTS

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

FIFTH SCHEDULE — *continued*

First column	*Second column*
Therapeutic product	*Cautionary information*
Dimethpyrindene	
Diphenhydramine	
Diphenylpyraline	
Doxylamine	
Embramine	
Flunarizine	
Homochlorcyclizine	
Isothipendyl	
Levocabastine	
Mebhydrolin	
Meclastine	
Meclozine	
Mepyramine	
Mequitazine	
Methdilazine	
Oxatomide	
Oxomemazine	
Phenindamine	
Pheniramine	
Phenyltoloxamine	
Promethazine	
Pyrathiazine	
Pyrrobutamine	
Thenalidine	
Thenyldiamine	
Thiazinamium	
Tolpropamine	

FIFTH SCHEDULE — *continued*

First column	*Second column*
Therapeutic product	*Cautionary information*
Tripelennamine	
Triprolidine	

SIXTH SCHEDULE

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

SEVENTH SCHEDULE

Regulation 52(1)(*b*)

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

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

Made on 14 July 2016.

KANDIAH SATKUNANANTHAM
Chairman,
Health Sciences Authority,
Singapore.

[HSA 401:04/05-000; HSA/LPPD/711:12/61-000;
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