



BERMUDA

PHARMACY AND POISONS AMENDMENT ACT 2013

2013 : 48

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- 29 Inserts Sixth Schedule
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WHEREAS it is necessary to amend the Pharmacy and Poisons Act 1979 to endeavour to ensure prescribing rights and requirements facilitate more affordable and accessible care; to improve the administration of the pharmacy sector; to ensure the Ministry has sufficient regulatory power to restrict and prevent the importation, distribution and sale of all drugs for medicinal use; to remove references to poisons; and related purposes;

Be it enacted by The Queen's Most Excellent Majesty, by and with the advice and consent of the Senate and the House of Assembly of Bermuda, and by the authority of the same, as follows:

### Citation

1 This Act, which amends the Pharmacy And Poisons Act 1979 ("the principal Act"), may be cited as the Pharmacy And Poisons Amendment Act 2013.

### Amends Section 2

2 Section 2 of the principal Act is amended by—

(a) inserting the following in proper alphabetical order—

“ “Association” means the professional association representing pharmacists in Bermuda;

“drug” means a substance or combination of substances used, or for use in or on the body of a person or animal—

(a) to prevent, diagnose, treat or mitigate a disease, disorder or abnormal physical or mental state or symptom of them; or

(b) to restore, correct or modify organic functions, and includes a prescribed substance or combination of substances;

“drug product” means a manufactured product that contains a drug including tablets, pills, capsules, caplets, creams, powders, transdermal patches or liquids;

“non-practising pharmacist” means a person who is registered as a pharmacist section 7A but who is not practising pharmacy in Bermuda;”.

(b) deleting the definition of “practitioner” and substituting—

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“practitioner” includes any of the professions listed in the Second Schedule;”.

(c) deleting the definition of “a prescription” and substituting the following—

“prescription” means a prescription issued by any of the practitioners listed in the Second Schedule;”.

(d) amending the definition of “registered pharmacist” by deleting “section 7(4)” and substituting “section 7(4) and (4B)”.

Amends section 4

3 Section 4 of the principal Act is amended—

(a) in subsection (1) by inserting the following after paragraph (a)—

“(aa) one member, who shall be a representative of the Association, appointed by the Minister after consulting with the Chief Medical Officer;”;

(b) in paragraph (c) by deleting “three” and substituting “four”.

Inserts section 4B

4 The principal Act is amended by inserting the following after section 4A—

“Protection from personal liability

4B A member of the Council shall not be personally liable for damages for anything done or omitted to be done in the discharge or purported discharge of the Council’s functions under this Act unless the act or omission was in bad faith.”.

Amends section 7

5 Section 7 of the principal Act is amended—

(a) in subsection (1) by deleting “Council pursuant to the provisions of the First Schedule” and substituting “Minister”;

(b) in subsection (3) by deleting “Council” and substituting “Registrar”;

(c) in subsection (4) by deleting “prescribed” where it first occurs and substituting “required”;

(d) by inserting the following after subsection (4A)—

“(4B) The Registrar may approve an application for re-registration under subsection (4A) and issue a certificate of re-registration to the person applying.”;

(e) in subsection (5)—

(i) by deleting paragraph (a) and substituting the following—

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- “(a) is fit and proper and possesses the appropriate qualifications and experience;”;
- (ii) by inserting “for passing a written exam in pharmacy set by the Council” after the word “Council” in paragraph (b);
- (f) by inserting the following after subsection (5)—
  - “(5A) A person applying for re-registration under subsection (4A) shall—
    - (a) apply in the form required by the Council;
    - (b) pay the appropriate fee;
    - (c) continue to meet the qualifications, experience and conduct as required in subsection (5);
    - (d) meet the minimum amount of continuing professional development as required by the Council; and
    - (e) meet the number of practice hours as required by the Council.”.
- (g) by deleting subsection (6) and substituting the following—
  - “(6) Where the Registrar refuses or fails to register a person who makes an application under subsection (4), or refuses or fails to re-register a person who makes an application under subsection (4A) (hereinafter in this section called “applicant”), the applicant may appeal to the Supreme Court.”.
- (h) by deleting subsection (7) and inserting the following—
  - “(7) An applicant may appeal to the Supreme Court under subsection (6) within 28 days after the decision is made (in this section referred to as “the appeal period”).
  - (7A) The Registrar’s decision to refuse to register or re-register, or failure to register or re-register, an applicant does not have effect until the expiration of the appeal period, or where an appeal is brought, until the appeal is decided or abandoned.”;
- (i) by deleting subsection (8) and substituting the following—
  - “(8) “appropriate fee” in subsections (4) and (5A) means the relevant fee prescribed in the Government Fees Regulations 1976.”.

Inserts section 7A

6 The principal Act is amended by inserting the following after section 7—

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“Re-registration as non-practising member

7A (1) A person who is registered under section 7(4) and is not practising pharmacy in Bermuda may re-register as a non-practising pharmacist in a form required by the Council and by paying the appropriate fee.

(2) The Registrar shall establish and maintain a register of non-practising pharmacists for the purposes of this Act.

(3) A person registered as a non-practising pharmacist shall not practise pharmacy in Bermuda.

(4) A non-practising pharmacist applying for re-registration to practise pharmacy shall—

- (a) apply in the form required by the Council;
- (b) pay the appropriate fee;
- (c) continue to meet the qualifications, experience and conduct requirements in section 7(5); and
- (d) meet the minimum amount and type of continuing professional development and practice hours as required by the Council.

(5) In subsection (1) “the appropriate fee” means the relevant fee prescribed in the Government Fees Regulations 1976.”.

Repeals and replaces section 8, 9 and 10

7 Sections 8, 9 and 10 of the principal Act are repealed and replaced with the following—

“Code of Conduct

8 (1) It shall be the duty of the Council to prepare, and from time to time as they think fit amend, a code of conduct which the Council considers to be conduct that is proper for registered pharmacists in a professional respect (hereinafter in this Act called “the Code”).

(2) The Council shall send by post to each registered pharmacist at his address on the register of pharmacists a copy of the Code and of any amendment made to the Code.

(3) In exercise of their powers under section 10A the Council shall, subject to subsection (4), be guided by any relevant provision of the Code.

(4) Where an inquiry has been conducted by the Council under sections 10A or 10B, the Council may find a person guilty of negligence, incompetence or other improper conduct notwithstanding that the conduct in question is not prohibited by the Code, but they shall not find a person guilty of improper conduct if that conduct is authorized by the Code.

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### Pharmacy Profession Complaints Committee

9 (1) There shall be established, in accordance with the Fifth Schedule, a committee to be known as the "Pharmacy Profession Complaints Committee" (hereinafter in this Act called "the Committee").

(2) The functions of the Committee are—

- (a) to receive and investigate, or cause to be investigated, complaints against any registered pharmacist including any allegation that—
  - (i) the pharmacist's registration was improperly obtained;
  - (ii) the pharmacist is guilty of professional misconduct;
  - (iii) the pharmacist is unfit to practise by reason of conviction of an indictable offence or adverse physical or mental health; or
  - (iv) the pharmacist is otherwise unfit to practise or to be registered; and
- (b) to perform such other functions as may be prescribed.

(3) The Committee may investigate any complaint based on matters alleged to have occurred—

- (a) inside or outside Bermuda; or
- (b) at any time, whether or not at a time when the person complained against was registered as a pharmacist.

(4) A complaint referred to in subsection (2)(a)—

- (a) shall be made by the complainant—
  - (i) if the complainant is a child or is physically or mentally unable to make the complaint, by the parent or guardian, friend or a person acting on behalf of the complainant; and
  - (ii) if the conduct complained of relates to a person who is dead, by the person's executor or personal representative;
- (b) shall be in writing and addressed to the Committee;
- (c) shall set out the matters alleged to constitute grounds for disciplinary action to be taken against the pharmacist who is the subject of the complaint;
- (d) may be required by the Committee to be in a form approved by the Committee.

(5) If the Committee considers that a complaint arose from a misunderstanding by the complainant or between the complainant and the pharmacist complained of, the Committee may, before proceeding further with the investigation of the complaint, require the parties to appear before it in order to

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discuss the matter with a view to clarifying the misunderstanding and resolving the matter informally.

(6) The Fifth Schedule has effect as to the appointment and proceedings of the Committee and other matters relating to the Committee.

Investigation of complaint by Committee

10 (1) Where a complaint under section 9(4) is not resolved informally as provided in section 9(5), the Committee shall investigate the complaint and determine whether, in its opinion, the complaint—

- (a) is frivolous or vexatious, is made in bad faith, is an abuse of process, or for any other reason, ought not to be referred to the Council; or
- (b) ought to be referred to the Council for decision.

(2) The Committee—

- (a) shall give written notice to the pharmacist who is the subject of the complaint that a complaint has been made, together with a summary of the matters alleged in the complaint;
- (b) shall request that the pharmacist who is the subject of the complaint show cause in writing, within a specified time after the notice is given, explaining why the matter should not be placed before the Council for determination; and
- (c) may take evidence from witnesses on oath or affirmation, administered by the Chairman.

(3) If the Committee determines that a complaint is frivolous or vexatious, is made in bad faith, is an abuse of process or otherwise ought not to be considered by the Committee, it shall dismiss the complaint and give written notice to the complainant of the dismissal and the reasons for the dismissal.

(4) If the Committee determines that a complaint ought to be referred to the Council for decision, the Committee shall, as soon as practicable, refer the matter to the Council.”.

Inserts sections 10A and 10B

8 The principal Act is amended by inserting the following next after section 10—

“Inquiry into complaint by Council

10A (1) If, pursuant to an investigation under section 10, the Committee places the matter before the Council for determination, the Council shall inquire into the matter.

(2) For the purposes of an inquiry of this section, the Council—

- (a) may take evidence from witnesses on oath or affirmation, and for that purpose the Chairman of the Council may administer an oath or affirmation;
- (b) shall afford the registered pharmacist and the Committee, or a member of the Committee, every facility—
  - (i) to appear before the Council;
  - (ii) to be represented by a barrister and attorney;
  - (iii) to call or cross-examine witnesses; and
  - (iv) generally to make a full defence or explanation in the matter of the complaint.

(3) Following its inquiry, the Council shall make a decision as to whether the complaint is proved or not proved, in whole or in part, together with reasons for its decision.

(4) If the Council decides that a complaint is not proved, in whole or in part, it shall dismiss the complaint to the extent that it is not proved.

(5) If the Council decides that a complaint is proved, in whole or in part, it shall record a finding to that effect and it may make any order of a disciplinary nature that it sees fit in respect of a pharmacist against whom the complaint is made, including an order—

- (a) admonishing the pharmacist;
- (b) suspending the pharmacist from practice as a pharmacist for such period as it sees fit or for an indefinite period;
- (c) striking the name of the pharmacist off the register;
- (d) imposing conditions or limitations with regard to the pharmacist's practice as a pharmacist.

(6) The Council shall give written notice, to the pharmacist against whom a complaint is made, of its decision under subsection (3) and any order made by the Council under subsection (5), together with reasons.

(7) The pharmacist against whom the complaint is made may appeal against a decision or order of the Council in the manner provided in section 14.

(8) Any proceedings in connection with the holding of an inquiry by the Council under this section shall, for the purpose of the provisions of the Criminal Code Act 1907 relating to perjury, be deemed to be judicial proceedings.

(9) A member of the Council who was involved in the matter complained of may not participate in an inquiry by the Council under this section.

(10) A person who is suspended from practice under this section shall, for the duration of the suspension, be deemed not to be registered.



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Inquiry by Council of its own initiative

10B (1) In the absence of a complaint, the Council may, of its own initiative, hold an inquiry into any matter referred to in section 9(2) that could have formed the subject of an investigation by the Committee.

(2) The provisions of section 10A that apply in respect of an inquiry by the Council under that section shall apply to an inquiry under this section with any necessary modification.”.

Amends sections 11 and 15

9 The principal Act is amended—

- (a) in section 11 by deleting “section 8” and substituting “sections 10A and 10B”;
- (b) in section 15 by deleting “section 8(2)” and substituting “sections 10A and 10B”.

Repeals and replaces section 12

10 The principal Act is amended by repealing and replacing section 12 with the following—

“Restoration of name to register

12 (1) A person whose name has been removed from the register under section 11, or whose name has been struck from the register, or who has been suspended from practice under section 10A or 10B, may make an application to the Council, in a form determined by the Council, for his name to be restored to the register or for his suspension to be terminated.

(2) An application under subsection (1) for the restoration of a name to the register of pharmacists shall not be made to, or be considered by, the Council—

- (a) within twelve months after the date of removal, striking off or suspension;
- (b) within twelve months after a previous application under that subsection; or
- (c) where the Council in the direction ordering the erasure appointed a period within which another application should not be made under that subsection, within that period.

(3) On receipt of an application, the Council shall decide whether to restore the applicant’s name to the register or to terminate his suspension, after considering the following matters—

- (a) the character and professional ability of the applicant;
- (b) the nature of the matter in respect of which the applicant’s name was struck from the register or for which the applicant was suspended;

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- (c) the conduct of the applicant after his name was struck from the register or after he was suspended;
  - (d) any other circumstances appearing to the Council to be relevant.
- (4) The Council shall give written notice to the applicant of its decision, together with reasons.
- (5) An applicant may appeal against the decision of the Council in the manner provided in section 14.”.

Repeals and replaces section 14

11 The principal Act is amended by repealing and replacing section 14 with the following—

“Appeals

14 (1) A person aggrieved by any decision of the Council referred to in subsection (2) may, within 28 days after the date on which the decision is given to the person by the Council, appeal to the Supreme Court against the decision.

(2) The person referred to in subsection (1) may appeal against the following decisions—

- (a) a decision not to issue or renew a registration certificate;
- (b) a decision not to issue a re-registration certificate;
- (c) a decision to remove the name of a person from the register;
- (d) a decision to remove, or alter, any entry in the register in respect of a person;
- (e) a decision not to restore a person’s name to the register;
- (f) a decision not to terminate a person’s suspension.

(3) On an appeal under this section the Supreme Court may make such order in the matter as it thinks proper, including an order as to the costs of the appeal.

(4) An order of the Supreme Court under subsection (2) is final.

(5) The practice and procedure to be followed in relation to an appeal under this section are as prescribed by rules of court.

(6) The Council may appear as respondent on such appeal and, whether they appear at the hearing of the appeal or not, they shall be deemed to be a part to the appeal for the purpose of enabling directions to be given as to the costs or expenses of the appeal.”.

Amends section 16

12 Section 16 of the principal Act is amended in subsection (2) by deleting “Council” and substituting “Registrar”.

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### Amends section 17

13 Section 17 of the principal Act is amended by deleting subsection (2) and substituting the following—

“(2) In subsection (1) “the appropriate fee” means the relevant fee prescribed in the Government Fees Regulations 1976.”.

### Amends section 23

14 Section 23 of the principal Act is amended—

(a) by repealing subsection (1) and replacing it with the following—

“(1) Subject to the provisions of this section, a prescription of any substance shall not be made by a practitioner unless it is on a valid prescription form which includes the information as provided in regulation 3A of the Pharmacy and Poisons (Control of Prescriptions) Regulations 1979.”;

(b) in subsections (3), (4), (5), (6), (10) and (11) by inserting “registered” immediately before “pharmacist” wherever it occurs;

(c) in subsection (7) by deleting “present ” and substituting “presented”.

### Inserts section 23A

15 The principal Act is amended by inserting the following after section 23—

“Validity of a prescription

23A A prescription shall be valid for one year from the date as shown on a valid prescription form.”.

### Repeals and replaces section 24

16 Section 24 of the principal Act is repealed and replaced with the following—

“Supply by registered pharmacist of equivalent medicines

24 (1) Where a registered pharmacist receives for execution a prescription which does not prohibit an alternative equivalent drug or drug product from being supplied under the prescription—

(a) it shall be required for the registered pharmacist to supply under the prescription any drug or drug product available to the pharmacist at the location of sale—

(i) which is in his opinion the chemical and therapeutic equivalent of the drug or drug product specified in the prescription; and

(ii) if taking all relevant factors into account, the price that he charges and accepts for the drug or drug product he supplies is less than that which he would have charged and accepted for the drug or drug product specified;

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- (b) it shall be lawful for the registered pharmacist to supply under the prescription any drug or drug product—
  - (i) which is in his opinion the chemical and therapeutic equivalent of the drug or drug product specified in the prescription; and
  - (ii) if taking all relevant factors into account, the prices that he charges and accepts for the drug or drug product he supplies is the same as that which would have charged and accepted for the drug or drug product specified.

(2) A drug or drug product supplied by a registered pharmacist under subsection (1) must be a drug or drug product accepted by the Council as the chemical and therapeutic equivalent of the drug or drug product specified in the prescription in question.”

Repeals section 31

17 Section 31 of the principal Act is repealed.

Inserts sections 31A, 31B, 31C, 31D and 31E

18 The principal Act is amended by inserting the following after section 31—

“Health and safety requirements

31A (1) For the purposes of sections 31B, 31C, 31D and 31E, a drug or drug product fails to comply with a general health and safety requirement if it is not reasonably safe having regard to all the circumstances including—

- (a) the manufacturer of a drug or drug product, or any regulatory authority that granted a drug or drug product marketing authorisation, issuing a recall or any form of notice of warning for the drug or drug product;
- (b) marketing authorisation of a drug or drug product granted by the regulatory authority in the United States, Canada or the European Union, or another jurisdiction that the United States, Canada or the European Union has a mutual recognition agreement with, is denied, suspended or discontinued due to reasons of quality, safety or efficacy;
- (c) the storage, distribution, supply, security, or handling of the product compromised its safety, quality or efficacy due to standards set by the manufacturer or regulatory authority that granted marketing authorization for the drug or drug product;
- (d) the drug or drug product is not properly labelled to allow for—
  - (i) its safe consumption;
  - (ii) the determination of—
    - (A) the amount of active ingredients;

- (B) its proper use;
  - (C) the content;
  - (e) any other risk to public or individual health as specified by the Minister after consultation with the Chief Medical Officer.
- (2) A person is guilty of an offence under this section if he—
- (a) supplies any drug or drug product which fails to comply with the health and safety requirement or any prescribed standard;
  - (b) offers or agrees to supply any such drug or drug product; or
  - (c) exposes or possesses such drug or drug product for supply,

and is liable on summary conviction to a fine of \$10,000 or imprisonment for 6 months, or both.

#### Orders and notices to prohibit supply of a drug or drug product

31B (1) The Minister may—

- (a) make orders (“prohibition orders”) prohibiting persons from supplying, or offering to supply, exposing for supply or possessing for supply any drug or drug product which the Chief Medical Officer considers is not safe and which are described in the orders;
- (b) serve on any person a notice (“prohibition notice”) prohibiting the person from supplying, or offering to supply, agreeing to supply, exposing for supply or possessing for supply any drug or drug product which the Chief Medical Officer considers is not safe and described in the notice;
- (c) serve on any person a notice (“notice to warn”) requiring the person to publish, in a form and manner and on occasions specified in the notice and at his own expense a warning about any drug or drug product so specified which the Chief Medical Officer considers is not safe and which the person supplies or has supplied.

(2) A person who contravenes a prohibition order, a prohibition notice or a notice to warn is liable on summary conviction to a fine of \$10,000 or to imprisonment for 6 months, or both.

#### Suspension notices

31C (1) Where the Minister has reasonable grounds for suspecting that any health and safety requirement provided in section 31A has been contravened in relation to any drug or drug product, he may serve a notice (“a suspension notice”) prohibiting the person on whom it is served, for such period ending not more than six months after the date of the notice as specified therein, from supplying the drug or drug product, offering to supply them, agreeing to supply them or exposing them for supply without the consent of the Minister.

(2) A suspension notice shall—

- (a) describe the drug or drug product in a manner to sufficiently identify it;
- (b) set out the grounds on which the Minister suspects that a safety provision has been contravened in relation to the drug or drug product; and
- (c) state that the person on whom the notice is served may apply under section 31D for an order setting aside the notice.

(3) The consent of the Minister under subsection (1) may impose such conditions on the doing of anything for which the consent is required as the Minister considers appropriate.

(4) Any person who contravenes a suspension notice is guilty of an offence and is liable on summary conviction to a fine of \$10,000 or to imprisonment for 6 months, or both.

#### Application to set aside a suspension notice

31D (1) Any person having an interest in any drug or drug product in respect of which a suspension notice is in force may apply to a magistrate for an order setting aside the notice.

(2) On an application under subsection (1), the magistrate shall not make an order setting aside the suspension notice unless he is satisfied that there has been no contravention of any safety provision in relation to any drug or drug product.

#### Power to obtain information

31E (1) If the Minister considers that, for the purpose of deciding whether to make, vary or revoke a prohibition order or to serve, vary or revoke a prohibition notice or to serve or revoke a notice to warn, he requires information which another person is likely to be able to furnish, the Minister may serve on the other person a notice requiring the person—

- (a) to furnish to the Minister within a period specified in the notice, such information as is so specified;
- (b) to produce such documents as are specified in the notice at a time and place so specified and to permit a person appointed by the Minister for the purpose of taking copies of the documents at that time and place.

(2) A person is guilty of an offence if he—

- (a) fails, without reasonable cause, to comply with a notice served on him under subsection (1); or
- (b) in purporting to comply with a requirement which by virtue of subsection (1)(a) is contained in a notice served on him under that

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subsection, furnishes information which he knows is false in a material particular or recklessly furnishes information which is false in a material particular.

- (3) A person guilty of an offence under—
- (a) subsection 2(a) of that subsection, is liable on summary conviction to a fine of \$10,000 or to imprisonment for 6 months; and
  - (b) subsection 2(b) of that subsection, is liable on summary conviction to a fine of \$15,000 or to imprisonment for 12 months.
- (4) No information obtained by virtue of this section shall be disclosed except—
- (a) for the purpose of any criminal proceedings or any investigation with a view to such proceedings;
  - (b) for the purpose of enabling the Minister to decide whether to make, vary or revoke safety regulations or a prohibition order or whether to serve, vary or revoke a prohibition notice or to serve or revoke a notice to warn; or
  - (c) in a prohibition notice, a notice to warn or a warning published as required by a notice to warn or in a warning about goods which is published by the Minister;

but the prohibition on disclosure imposed by this subsection does not apply to publicised information.

(5) A person who discloses information in contravention of subsection (4) is liable on summary conviction to a fine of \$10,000 or to imprisonment for 6 months, or both.”

Amends section 46

19 Section 46 of the principal Act is amended in paragraph (a) by inserting the following after subparagraph (ix)—

“(x) the name of the practitioner who issued the prescription;”.

Amends section 48

20 Section 48(1) of the principal Act is amended—

- (a) in paragraph (g) by deleting “Third, Fourth or Fifth” and substituting “Third or Fourth”;
- (b) by inserting the following after paragraph (g)—
  - “(h) generally for carrying out the purposes of sections 31A, 31B, 31C, 31D, 31E, 51, 51A and 51B.”.

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Amends section 49

21 Section 49(2) of the principal Act is amended by deleting “to the relevant professional body for such action as that body may think fit to take” and substituting “to the Council in the case of a registered pharmacist, or to the relevant professional body in the case of a practitioner, for such action as the Council or that body may think fit to take”.

Repeals and replaces section 51

22 Section 51 of the principal Act is repealed and replaced with the following—

“Inspections

51 (1) It shall be the duty of the Minister, by means of inspection and otherwise, to take all reasonable steps to enforce, and secure compliance by registered pharmacists and others with the provisions of this Act or any regulation, and the Minister shall for that purpose appoint such number of inspectors as in his opinion is required.

(2) Any inspector may, for the purposes of enforcement of this Act or any regulations, make test purchases or otherwise ascertain whether any provisions of this Act or any regulations or of an order under this Act are being complied with.

(3) An inspector appointed under this section who has reasonable cause to believe that an offence under this Act or regulations has been committed shall, for the purpose of enforcing and securing compliance with the said provisions have power—

- (a) at all reasonable times and on production, if required, of his credentials, enter any registered pharmacy or place of business (other than premises or parts of premises used as a dwelling house) and while there he may—
  - (i) inspect any drug or drug product found;
  - (ii) examine any procedure;
  - (iii) seize and detain drugs or drug products for testing;
  - (iv) seize and detain goods or documents which he believes may be required as evidence in proceedings under this Act;
  - (v) for the purpose of exercising his powers to seize drugs or drug products under this section and to the extent that it is reasonably necessary in order to ensure compliance with any provision of this Act, require any person having authority to do so to break open any container, and if the person does not comply, the inspector may do so himself.

(4) An inspector who seizes drugs, drug products or documents in exercise of his powers under subsection (3) shall, in a written statement specifying the nature and amount of items seized, inform the person from whom they are seized.



(5) For the purpose of proceedings taken or transactions made under this Act, the written statement of an inspector given under subsection (4) has effect as a receipt for the drug, drug products or documents seized.

(6) A magistrate who is satisfied by sworn information in writing that there are reasonable grounds to believe that—

- (a) goods, books or documents which an inspector has power to inspect are on any premises and that their inspection is likely to disclose evidence of the commission of an offence under this Act or the regulations; or
- (b) an offence under this Act or the regulations has been, is being, or is about to be committed on any premises;

and that—

- (c) admission to the premises has been or is likely to be refused and that notice of intention to apply for a warrant under this subsection has been given to the occupier; or
- (d) an application for admission or the giving of the notice mentioned in paragraph (c) would defeat the object of the entry or that the premises are unoccupied or that the occupier is temporarily absent and it might defeat the object of the entry to await his return,

may by warrant under his hand, which shall continue in force for a period of one month, authorise any inspector to enter the premises, if need be by force.

(7) An inspector who enters premises by virtue of this section may take with him such other persons and equipment as appears necessary to him, and on leaving premises which he enters by virtue of a warrant under subsection (6), where either the premises are unoccupied or the occupier is temporarily absent, he shall affix a notice in a conspicuous place stating that the premises were entered for the purpose of this section, and as far as practicable shall leave the premises as effectively secured against trespassers as he found them.

(8) A person who—

- (a) wilfully obstructs an inspector acting in the exercise of any power conferred on him under subsections (3) to (7);
- (b) wilfully fails to comply with any requirement properly made to him by an inspector under subsections (3) to (7);
- (c) without reasonable cause fails to give an inspector acting under subsections (3) to (7), such assistance or information as he may reasonably require of the person for the performance of the inspector's functions;
- (d) in giving information as mentioned in paragraph (c) makes a statement which he knows to be false;

- (e) not being an inspector purports to act as an inspector under this Act;
  - (f) discloses to another person, where the disclosure is not made in the performance of his duty—
    - (i) information with respect to a manufacturing process or trade secret obtained by him in premises which he has entered by virtue of subsections (3) to (7); or
    - (ii) information otherwise obtained by him under this Act,
- is guilty of an offence and is liable on summary conviction to a fine of \$10,000 or imprisonment for 6 months, or both.

(9) An inspector appointed under this section shall have power with the consent of the Minister to institute summary proceedings in respect of an offence against this Act or any regulation, and to conduct any such proceedings notwithstanding that he is not a barrister and attorney.

(10) If a person wilfully delays or obstructs an inspector in the exercise of any of his powers under this section, or refuses to allow any sample to be taken in accordance with the provisions of this section, or fails without reasonable excuse to give any information which he is duly required under this section to give, he is guilty of an offence against this Act.”.

Inserts sections 51A and 51B

23 The principal Act is amended by inserting the following after section 51—

“Notice of test

51A (1) Where drugs or drug products seized or purchased by an inspector in pursuance of this Act are submitted to a test, the inspector shall—

- (a) if the drugs or drug products were seized, inform the person from whom they were seized of the result of the test;
- (b) if the drugs or drug products were purchased and the test leads to proceedings for an offence under this Act, inform the person from whom the goods were purchased of the result of the test;

and where as a result of the test proceedings for an offence are instituted against a person, the inspector shall allow the person to have the goods tested independently if it is reasonably practicable to do so.

(2) The Minister may by order provide for the testing of drugs or drug products seized or purchased by an inspector in pursuance of this Act and in particular may in those orders provide that the test be carried out at the Ministry’s expense in a manner, by a person, and at a laboratory or testing facility specified in the order.

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### Compensation

51B (1) Where in the exercise of his powers under section 51 an inspector seizes and detains any drugs or drug products, and the owner suffers loss by reason of the goods being seized or by reason that, during the detention, the goods are lost or damaged or deteriorate, unless the owner is convicted of an offence under this Act committed in relation to the goods, the owner is entitled to compensation for the loss so suffered.

(2) Any disputed question as to the right to or the amount of any compensation payable under this section shall on the written application of the owner or of the Attorney-General be determined as follows—

- (a) if the amount of the compensation claimed does not exceed \$10,000, by a magistrate; or
- (b) if the amount of the compensation claimed exceeds \$10,000, by a judge of the Supreme Court,

in like manner as if the magistrate or the judge were a single arbitrator appointed pursuant to the provisions of the Arbitration Act 1986, and the provisions of that Act shall apply accordingly.”.

### Amends First Schedule

24 The First Schedule to the principal Act is amended—

- (a) by deleting paragraph 9 and substituting the following—

“9 (1) The Council may, in its discretion, appoint from among its own members or from among other persons, such number of committees as it thinks fit for purposes which, in the opinion of the Council, would be more expediently carried out or managed by such committees.

(2) The Chairman of any committee appointed under subsection (1) shall be a member of the Council.”.

- (b) by inserting the following after paragraph 9—

“10 Where the Council has resolved to recommend to the Minister that additional drugs for listing under, or removal from, the Third and Fourth Schedules, the Minister may, by Notice in the Gazette, provisionally list, or remove, the drugs in the Third and Fourth Schedules, as the case may be, and such drugs shall be considered to be listed, or removed, in the Schedules for a period not exceeding 30 days or until the Minister issues an Order either adding to, or deleting from, the Schedules such drugs, whichever occurs earlier.”.

### Repeals and replaces Second Schedule

25 The Second Schedule to the principal Act is repealed and replaced by the following—

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“SECOND SCHEDULE

(Section 2)

LIST OF PRACTITIONERS

Physician- for the purposes of medical treatment of human beings

Dentist- for the purposes of dental treatment of human beings

Veterinary Practitioner- for the purposes of animal treatment

Optometrist- subject to the restrictions and requirements under section 10 and Schedule 2 of the Optometrists and Opticians Act 2008

Advanced Practice Nurse- subject to the restrictions and requirements under 8B(1) and (2) of the Nursing Act 1997

Amends Third Schedule

26 The Third Schedule to the principal Act is amended by deleting “and the Fourth and Fifth Schedules” in the Note to the Schedule and substituting “and the Fourth Schedule”.

Amends Fourth Schedule

27 The Fourth Schedule to the principal Act is amended by deleting “and the Fourth and Fifth Schedules” in the Note to Part I of the Schedule.

Repeals and replaces the Fifth Schedule

28 The Fifth Schedule to the principal Act is repealed and replaced by the following—

“FIFTH SCHEDULE

(Section 9)

PHARMACY PROFESSION COMPLAINTS COMMITTEE

1 The Committee shall consist of three members appointed by the Minister, as follows—

(a) one from a list of at least three registered pharmacists in good standing who is nominated by the Association;

(b) one from a list of at least three registered pharmacists in good standing nominated by the Council;

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(c) one professionally qualified person who is not a registered pharmacist.

2 A person who is a member of the Council may not be appointed as a member of the Committee.

3 Appointment as a member under paragraph 1 shall be for a term not exceeding three years and a member is eligible for reappointment.

4 The Minister may appoint a second person to act as alternate to a member appointed under paragraph 1.

5 An alternate member shall be appointed in accordance with the requirements for the appointment of the member, and his term of appointment shall, if not sooner terminated, end at the expiration of the term of the member.

6 There shall be a Chairman of the Committee who shall be appointed annually by the Minister from among the members of the Committee to hold office until 31 December of the year for which he was appointed, and who shall be eligible for reappointment as Chairman.

7 If at any time the Chairman ceases to be a member of the Committee, or for any other reason ceases to be the Chairman, the Minister shall, as soon as may be, appoint from among the members of the Committee another person to be Chairman in his stead.

8 Three members of the Committee shall form a quorum at any meeting.

9 (1) Where any complaint is before the Committee, a member of the Committee shall advise the Chairman if he is personally acquainted with the facts of the case and may, with leave of the Chairman, withdraw on that ground or for any other reason which the Chairperson deems sufficient; and the Chairman may himself withdraw on any such ground.

(2) Where a member has so withdrawn, the Chairman may request the Minister to appoint a member of equal standing as the withdrawn member to be a member of the Committee for the purpose of those proceedings, and the Minister may make such appointment, whereupon the person so appointed shall be deemed to be a member of the Committee for such purpose.

10 Fees shall be paid to members of the Committee in accordance with the Government Authorities Fees Act 1971.

11 The validity of any act or proceedings of the Committee shall not be affected by any vacancy among the members of the Committee or by any defect in the appointment of a member of the Committee or of the Chairperson.

12 The Committee shall, not later than 31 January after the end of each calendar year, submit a report on its activities for the preceding year to the Council.

13 Subject to this Act, the Committee shall regulate its own proceedings.”.

Inserts Sixth Schedule

29 The principal Act is amended by inserting the following after the Fifth Schedule—

“SIXTH SCHEDULE

(Section 26B)

PROHIBITION ORDERS, PROHIBITION NOTICES AND NOTICES TO  
WARN

PART I  
PROHIBITION ORDERS

1 If the Minister proposes to make a prohibition order (“an order”), then, subject to paragraph 5, he shall before he makes the order—

- (a) publish, in such manner as he thinks fit a notice stating—
  - (i) that he proposes to make the order and, in such terms as he thinks fit, the proposed effect of the order; and
  - (ii) that any person may make representations in writing to the Minister about the proposed order before a date specified in the notice (which must be after the expiration of the period of 28 days beginning with the date of the first publication of the notice); and
- (b) consider any such representations made within that period.

2 The effect of an order must not be more restrictive, but may be less restrictive, than the proposed effect of it as stated in the notice.

3 Without prejudice to the power to make a further order and subject to paragraph 4, an order shall cease to have effect at the expiration of a period specified in the order which must not be longer than 12 months beginning with the date on which the order comes into force.

4 An order may revoke a previous order or may vary it otherwise than providing for it to be in force after expiration of 12 months beginning with the date of the coming into force of the previous order.

5 Paragraphs 1 and 2 shall not apply to an order if the order contains a statement that in the opinion of the Minister the risk of danger connected with the drug or drug product to which the order relates is such that the order must be made without delay.

PART II  
PROHIBITION NOTICES

*Preliminary*

- 6 In this Part—
- “notice” means a prohibition notice;
  - “notification” means a notification in writing;
  - “the trader” in relation to a proposed notice or an actual notice means the person on whom the proposed notice is proposed to be served or on whom the actual notice has been served.
- 7 A notice must specify the date on which it comes into force.

*General Procedure*

8 If the Minister proposes to serve a notice in respect of any drug or drug product, then, subject to paragraph 14, he shall before he serves the notice serve on the trader a notification—

- (a) stating that the Minister proposes to serve on him a notice in respect of the drug or drug product; and
- (b) specifying the drug or drug product in a manner sufficient to identify them and stating that, for the reasons set out in the notification, the Minister considers that the drug or drug products are not safe; and
- (c) stating that the trader may make representations, in writing or both in writing and orally, for the purpose of satisfying the Minister that the drug or drug product is safe but that if the trader intends to make such representations he must, before the expiration of the period of 14 days beginning with the day when the notification is served on him, inform the Minister of his intention indicating whether the representations are to be in writing only or both in writing and oral.

9 Subject to paragraph 14, the Minister shall not serve a notice on the trader in respect of any drug or drug product before the expiration of the period of 14 days beginning with the day on which the Minister served on him a notification in pursuance of paragraph 8 relating to the drug or drug products; and if within that period the trader informs the Minister as mentioned in paragraph 8(c), then—

- (a) the Minister shall not serve a notice on the trader in consequence of the notification before the expiration of the period of 28 days beginning with the day aforesaid; and

- (b) if during that period the trader makes to the Minister such written representations as are mentioned in paragraph 8(c) the Minister shall not serve a notice on the trader in consequence of the notification before the Minister has considered the report of a person appointed in pursuance of paragraph 10 in consequence of the representations.

10 Where, in consequence of the service on the trader of a notification in pursuance of paragraph 8, the trader informs the Minister as mentioned in paragraph 8(c) within the period so mentioned and makes to the Minister within that period or the fourteen days beginning with the end of that period such written representations as are so mentioned, the Minister shall—

- (a) appoint any person to consider the written representations; and
- (b) if the trader informed the Minister in pursuance of paragraph 8(c) that the representations would be both written and oral, inform the trader of the place and time (which must not be before the expiration of the fourteen days and of seven days beginning with the day when the information is given to the trader) at which the oral representations may be made to the person appointed;

and the trader or his representative may at that place and time make to the person appointed oral representations for the purpose of satisfying the Minister that the drug or drug product in question is safe and may call and examine witnesses in connection with the representations.

11 The person appointed in pursuance of paragraph 10 to consider written representations with respect to any drug or drug product shall, after considering the representations, any oral representations made in pursuance of that paragraph with respect to the drug or drug product and any statements made by witnesses in connection with the oral representations, make a report (including recommendations) to the Minister about the representations and the proposed notice.

12 If at any time after the Minister has served a notification on the trader in pursuance of paragraph 8 the Minister decides not to serve a notice on him in consequence of the notification, the Minister shall inform him of the decision; and after the Minister informs him of the decision the notification and anything done in consequence of it in pursuance of the preceding paragraphs shall be disregarded for the purposes of those paragraphs.

13 Where a notification is served on the trader in respect of any drug or drug product in pursuance of paragraph 8, a notice served on him in consequence of the notification may relate to some only of those the drug or drug product.



*Special Procedure*

14 Paragraphs 8 to 13 do not apply to a notice which contains a statement that the Minister considers that the risk of danger connected with the drug or drug product to which the notice relates is such that the notice must come into force without delay; and references to a notice in paragraphs 15 to 18 are to a notice containing such a statement.

15 A notice in respect of any drug or drug product must—

- (a) state that, for the reasons set out in the notice, the Minister considers that the drug or drug product is not safe; and
- (b) state that the trader may, at such time as the trader thinks fit, make representations in writing to the Minister for the purpose of satisfying him that the drug or drug product is safe.

16 If representations in writing about a notice are made by the trader to the Minister, the Minister shall consider the representations and either revoke the notice and inform the trader that he has revoked it or—

- (a) appoint a person to consider the representations; and
- (b) serve on the trader a notification stating that he may make to the person appointed oral representations for the purpose mentioned in paragraph 15 and specifying the place and time (which, except with the agreement of the trader, must not be before the date of service of the notification) at which the oral representations may be made,

and the trader or his representative may at that place and time make to the person appointed oral representations and may call and examine witnesses in connection with the representations.

17 The person appointed in pursuance of paragraph 16 to consider written representations with respect to any drug or drug product shall, after considering the representations, any oral representations made in pursuance of that paragraph with respect to the goods and any statements made by witnesses in connection with the oral representations, make a report including recommendations to the Minister about the representations and the notice in question.

18 Where the Minister has appointed a person in pursuance of paragraph 16 to consider any representations relating to a notice then, without prejudice to the operation of paragraphs 19 and 20, paragraphs 16 and 17 shall not apply to any subsequent representations in writing about the notice.

*Other Representations*

19 If at any time the trader on whom a notice has been served makes representations in writing to the Minister for the purpose of satisfying him that the drug or drug product to which the notice relates is safe and, by virtue of paragraph 18, paragraph 16 does not apply to the representations, the Minister shall consider the representations and serve on the trader, before the expiration of one month beginning with the day when the Minister receives the representations, a notification stating—

- (a) that the Minister will revoke the notice or vary it or declines to do so; or
- (b) that the Minister has appointed a person to consider the representations and that the trader may make to the person appointed, at a place specified in the notification and a time so specified (which, except with the agreement of the trader, must not be before the expiration of the period of twenty-one days beginning with the date of service of the notification), oral representations for the purpose,

and the trader or his representative may at that place and time make to the person appointed oral representations and may call and examine witnesses in connection with the representations.

20 The person appointed in pursuance of paragraph 19 to consider written representations with respect to any drug or drug product shall, after considering the representations, any oral representations made in pursuance of that paragraph with respect to the drug or drug product and any statements made by witnesses in connection with the oral representations, make a report including recommendations to the Minister about the representations and the notice in question.

*Miscellaneous*

21 The Minister may revoke or vary a notice by serving on the trader a notification stating that the notice is revoked or, as the case may be, is varied as specified in the notification; but the Minister shall not have power to vary a notice so as to make the effect of the notice more restrictive for the trader.

22 The Minister shall consider any report made to him in pursuance of paragraph 17 or 20 and, after considering the report, inform the trader of his decision with respect to the notice in question.

PART III  
NOTICES TO WARN

23 If the Minister proposes to serve on a person a notice to warn in respect of any drug or drug product, the Minister shall, before he serves the notice, serve on the person a notification in writing—

- (a) containing a draft of the notice and stating that the Minister proposes to serve on the person such a notice in the form of the draft;
- (b) stating that, for the reasons set out in the notification, the Minister considers that the drug or drug product specified in the draft is not safe; and
- (c) stating that the person may make representations, in writing or both in writing and orally, for the purpose of satisfying the Minister that the drug or drug product is safe but that if the person intends to make such representations he must, before the expiration of the period of fourteen days beginning with the day when the notification is served on him, inform the Minister of his intentions indicating whether the representations are to be in writing only or both in writing and oral.

24 Paragraphs 9 to 13 and 21 shall with the necessary modifications have effect in relation to a notice to warn as they have effect in relation to a prohibition notice but as if—

- (a) the reference to paragraph 14 in paragraph 9 were omitted;
- (b) for the references to paragraph 8 in paragraphs 9, 10, 12 and 13 there were substituted references to paragraph 23;
- (c) in paragraph 13 for the words from “relate” onwards there were substituted the words “be less onerous than the draft of the notice contained in the notification”; and
- (d) in paragraph 21 the words “or vary” and the words from “or, as” onwards were omitted.”

**Repeal of Part VII (control of poisons) and amendments related to or consequential on repeal**

30 (1) The following provisions of the principal Act are repealed—

- (a) Part VII of the principal Act (comprising of sections 32 to 44);
- (b) the definition of poison in section 2; and
- (c) section 48(1)(e).

(2) The following provisions of the principal Act are amended as follows—

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- (a) the title and section 1, by deleting "and Poisons";
  - (b) the definition of "dispense" in section 2, by deleting "or a poison" in both places;
  - (c) section 45(1), by deleting "or poison";
  - (d) section 45(2), by deleting "or poison" wherever it occurs;
  - (e) section 46, by deleting "or poison";
  - (f) section 47, by deleting "or poison";
  - (g) the heading of section 48, by deleting "and VII";
  - (h) section 48(1)(a) and (b), by deleting "or a poison";
  - (i) section (j)(i) in section 48(1)(c) and (d), deleting "or poisons" in all three places;
  - (j) section 48(1)(f), by deleting "and poisons" wherever it occurs;
  - (k) section 48(1)(g), by deleting "or Fifth" and inserting "or" between "Third" and "Fourth";
  - (l) the heading to section 49, by deleting "and poisons";
  - (m) section 49(1), by deleting "or any poison";
  - (n) section 49(2)(a), by deleting "or a poison";
  - (o) section 51(2)(a), by deleting "or the place of business of any licensed seller of poisons"; and
  - (p) section 54(2), by deleting "or Fifth" and substituting "or" between "Third" and "Fourth".
- (3) Section 55(2) of the principal Act is amended by deleting "32, 37, 38, 40, 42 to 46: and substituting "45, 46,".
- (4) The Pharmacy and Poisons (Licensed Sellers of Poisons) Regulations 1979 are revoked.
- (5) Wherever the words "Pharmacy and Poisons" occur in any statutory provision, other than this Act and the principal Act before the amendment of this Act, in relation to the title of an Act or regulations, the words "and Poisons" are deleted.

### Consequential amendments

31 (1) The Pharmacy and Poisons (Control of Prescriptions) Regulations 1979 are amended—

- (a) by inserting the following after regulation 3—

"Valid prescription form

3A A valid prescription form shall contain—

- (a) the name and address of the patient, including the age of the patient if the patient is under 12 years of age;

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- (b) the name of the drug, or when necessary the ingredients, and the strength where applicable;
- (c) the quantity of the drug to be dispensed;
- (d) the dosage instructions for use by the patient which shall include a specific frequency or interval or maximum daily dose;
- (e) the name, initials, address and telephone number of the practitioner;
- (f) the date on which the prescription is written;
- (g) the practitioner's signature;
- (h) the refill authorization shall indicate the specific number of refills in the manner provided in regulation 4;
- (i) the ability to indicate, in the format required by the Chief Medical Officer, if a substitution permitted in section 24 of the Pharmacy and Poisons Act 1979 is not allowed. ”;

(b) by revoking regulation 4 and replacing it with the following—

“Valid repeat prescriptions

4 Where a prescription is to be repeated, the practitioner shall initial and circle thereon the specific number of times (not exceeding four) that prescription is to be repeated and such prescriptions shall for the purpose of repeats be invalid if instructions in respect of repeats are omitted from the prescription form.”.

(2) The Government Authorities (Fees) Act 1971 is amended by inserting the following after the item relating to the “Permanent Police Tribunal”—

“Pharmacy Complaints Committee - established by section 9 of the Pharmacy and Poisons Act 1979”.

(3) The Pharmacy and Poisons (Registration of Pharmacists) Regulations 1979 are amended by—

- (a) in regulation 4 by deleting “to the Registrar an application in accordance with Form A” and substituting “an application approved by the Council to the Registrar”;
- (b) revoking Form A in the Schedule.

(4) Head 45 of the Government Fees Regulations 1976 is revoked and replaced with the following—

“Head 45  
Pharmacy and Poisons Act 1979

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“ (1) Registering as a pharmacist under section 7—

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(a) on registration	\$57
(b) biennially on the anniversary of registration	\$57
(2) Changing registration from non-practising to practising pharmacist under section 7B	\$57
(3) Re-registering a non-practising pharmacist under section 7B	\$28
(4) Registering premises as a pharmacy under section 17	\$111

”.

### Commencement

32 (1) Section 16 comes into operation on such date as the Minister responsible for health appoints by notice in the Gazette.

(2) The repeal of Part VII (control of poisons) and amendments related to or consequential on the repeal in section 30 shall take effect on the same day the Pesticides Safety Act 2009 comes into operation.

[Assent Date: 24 December 2013]

[Operative Date: 24 December 2013]