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BARBADOS MEDICAL PRODUCTS ACT, 2026

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BARBADOS

A Bill entitled

An Act to establish the Barbados Medical Products Authority and provide for the regulation of medical products.

ENACTED by the Parliament of Barbados as follows:

PART I

PRELIMINARY

Short title

1. This Act may be cited as the *Barbados Medical Products Act, 2026*.

Interpretation

2. In this Act,

"Authority" means the Barbados Medical Products Authority established by section 6;

"biological medical product" means a product, derived from a biological source, that has therapeutic, prophylactic or diagnostic properties and includes vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins;

"Board" means the Barbados Medical Products Board established by section 10;

"chemical precursor" or "chemical substance" means a substance which can be used in any of the chemical processes involved in the production, manufacture or preparation of controlled drugs, psychotropic substances or substances having similar effect;

"Chief Executive Officer" means the person appointed as the head of the Authority in accordance with section 12;

"clinical trial " means an investigation in respect of a medical product for use in humans that involves human subjects and that is intended to discover or verify the clinical, pharmacological or pharmacodynamic effects of the drug, identify any adverse events in respect of the medical product, study its absorption, distribution, metabolism and excretion, or ascertain the safety or efficacy of the medical product;

"cosmetics" means a product intended to be applied to the human body for the purpose of cleaning, perfuming, beautifying, promoting attractiveness, changing appearance, protecting or altering appearance without affecting the body's structure or functions or keeping the external parts of the body in good condition, and includes dental products;

"dental practitioner" means a person who is licensed under the *Dental Registration Act*, Cap. 367;

"drug" means any substance or mixture of substances manufactured, sold or represented, presented or intended for use

(a) in the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or the symptoms thereof in humans or animals;

(b) in restoring, correcting or modifying physiological functions in human or animals by exerting a pharmacological, immunological or metabolic action;

(c) as a component of any medical device used in the diagnosis, treatment, mitigation or prevention of a disease or disorder, and which exerts a pharmacological, immunological or metabolic action;

"extemporary medicine" means a medical product manufactured in a pharmacy for an individual patient according to a doctor's prescription or an order of a healthcare institution, or both, or a medical product manufactured according to a written description of the process (a descriptive medical product) where no commercially suitable licensed product is available;

"falsified medical product" means a medical product the identity, composition or source of which is false or has been misrepresented;

"herbal medicine" means a medical product containing as active ingredients exclusively plant substances or herbal preparations or a combination thereof;

"inspector" means an inspector appointed under section 60;

"licence" means a licence issued by the Authority under this Act;

"marketing authorisation" means the approval of a medical product for marketing after the medical product has undergone a process of evaluation to determine its safety, efficacy and quality, and the appropriateness of the medical product information;

"medical device" means any instrument, apparatus or contrivance including components, parts or accessories thereof manufactured, sold or represented for the use in the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state or the symptoms thereof in man or animal;

"medical practitioner" has the meaning assigned to it by section 2 of the *Medical Profession Act, 2011* (Act 2011-1);

"medical product" means a substance or combination of substances, medicines, biologics, diagnostics, and medical devices intended for use in the diagnosis, treatment, mitigation, or prevention of diseases or medical conditions in humans or animals and includes

(a) biological medical products;

(b) herbal medicines;

(c) extemporary medicines;

(d) medicated cosmetics;

(e) veterinary medical products; and

(f) vaccines;

(g) tobacco and tobacco products;

(h) cannabinoids; and

(i) poisons;

"medicated cosmetics" means products that have both cosmetic and therapeutic, medical or drug-like effects and are intended to have a beneficial effect on skin health and beauty;

"Minister" means the Minister responsible for Health;

"mutual recognition procedure" means a procedure for recognition of regulatory decisions granted in respect of a medical product by

(a) a regulatory authority in another jurisdiction, which is equivalent to the Authority, and recognised by the Authority; and

(b) the Authority, and recognised by a regulatory authority in another jurisdiction, which is equivalent to the Authority;

"narcotics" means

(a) a class of drugs derived from the opium poppy, including morphine, codeine, oxycodone, or synthetic substances that have similar effects, or substances listed in Part I of the *First Schedule* to the *Drug Abuse (Prevention and Control) Act*, Cap. 131; and

(b) a substance listed in Schedules I-IV of the United Nations Single Convention on Narcotic Drugs (1961) as amended by the 1972 Protocol or any other conventions recognised by the Authority;

"pharmacist" has the meaning assigned to it by section 2 of the *Pharmacy Act*, Cap. 372D;

"poison"

(a) means a substance which is used for medical purposes but when introduced into the body in a sufficient quantity, is capable of causing death, injury or harm to organs or bodily functions; and

(b) includes a substance as such designated by the Authority;

"practitioner" means a medical practitioner, dental practitioner or veterinary surgeon;

"psychotropic substances" means

(a) a class of substances that affects mental processes, such as perception, mood, consciousness, cognition, and behaviour, and includes

stimulants, depressants, hallucinogens and any substance listed in Part II of the *First Schedul*e to the *Drug Abuse (Prevention and Control) Act*, Cap. 131; and

(b) any substance listed in the four schedules of the Convention on Psychotropic Substances of 1971;

"qualified technical person" means a person designated to ensure that medical products are manufactured and released in accordance with regulatory requirements, including Good Manufacturing Practice;

"quality management system" means a set of policies, processes and procedures for planning and execution of the core functions of the Authority;

"Registrar" means the Registrar of Companies;

"substandard medical product" means a medical product that fails to meet its quality standards or specifications or both;

"tobacco products" has the meaning assigned to it by section 2 of the *Health Services Act*, Cap. 44;

"Tribunal" means the Barbados Medical Products Appeals Tribunal established under section 62;

"vaccine" means a biological preparation that improves immunity to a particular disease;

"veterinary medical product" means a substance or combination of substances used in animals for therapeutic, prophylactic or diagnostic purposes;

"veterinary surgeon" has the meaning assigned to it by section 2 of the *Veterinary Surgeons (Registration) Act*, Cap. 374.

Construction

3. Where a conflict arises between this Act and another enactment, this Act shall prevail.

Objects of Act

4. The objects of this Act are to provide for the manufacture, regulation, investigation, inspection, registration, distribution, importation, exportation, traceability, monitoring and control of medicines, controlled substances, medical devices, *in vitro* and *in vivo* diagnostics and other medical products, clinical trials and related matters in the public interest.

Application

5.(1) This Act shall apply to all regulatory functions related to medical products including:

(a) registration and marketing authorisation;

(b) safety monitoring of medical products;

(c) market surveillance, and control of medical products including

(i) control of the import, export, storage, sale, distribution, and use of medical products; and

(ii) the management of unfit, substandard and falsified medical products;

(d) monitoring for compliance with quality standards of good practices for the licensing of persons and establishments throughout the medical products supply chain;

(e) inspection of establishments throughout the medical products supply chain;

(f) laboratory testing of medical products to assess the quality, efficacy and safety;

(g) clinical trials oversight;

(h) provision of lot release services;

(i) regulation of internet pharmacies; and

(j) regulation of nuclear medicine.

(2) This Act shall apply to

(a) premises used in the manufacture, storage, labelling and packaging of active pharmaceutical ingredients and raw materials used in the manufacture of medical products; and

(b) cleaning and laboratory chemicals used in the premises referred to in paragraph *(a).*

PART II

ADMINISTRATION

Establishment of Authority

6.(1) There is established an authority to be known as the Barbados Medical Products Authority.

(2) The Authority is a body corporate to which section 21 of the *Interpretation Act*, Cap. 1 applies.

Functions of Authority

7. The Authority shall

(a) regulate medical products, and in particular, ensure compliance with quality standards relating to

(i) the manufacture, storage, sale, distribution, use, import, export and labelling of medical products, which shall be in the English Language; and

(ii) the packages and raw materials used in the manufacture of medical products;

(b) monitor and control antiseptics, disinfectants, sterilants, and other chemical substances used in pharmaceutical manufacturing settings which fall under the scope of the Authority;

(c) monitor and control chemical substances that can be used in or intended, directly or indirectly, for the illicit manufacture, preparation or extraction of narcotic drugs or psychotropic substances, as well as to prevent and penalise the diversion and illegal manufacture of these chemical substances;

(d) grant marketing authorisation for approved medical products;

(e) create, maintain and publish a register of approved human and veterinary medical products;

(f) create, maintain and publish registers of licences, certificates and permissions issued under this Act;

(g) establish and publish a list of prohibited medicated cosmetics;

(h) establish the quality assurance and quality control of medical products regulated under this Act through designated quality control laboratories when necessary;

(i) create, maintain and publish a register of approved clinical trials;

(j) conduct pharmacovigilance and post-marketing surveillance for safety and quality of medical products;

(k) follow up and analyse information on the use of medical products that are subject to global drug safety monitoring;

(l) regulate and analyse information used in the promotion, advertising and marketing of medical products;

(m) regulate the use of unregistered products for clinical trial purposes, compassionate use and orphan drugs;

(n) regulate internet pharmacies;

(o) regulate nuclear medicine and, in particular, provide guidelines for the use, and the disposal of, contaminated articles;

(p) provide lot release services to manufacturers of medical products;

(q) disseminate information on quality and safety of products regulated under this Act to health professionals and other concerned persons;

(r) establish and maintain relevant quality control laboratories in strategic areas of Barbados as may be necessary for the performance of its functions under this Act;

(s) determine fees for services rendered by the Authority under this Act;

(t) establish technical advisory committees as the Authority may deem necessary;

(u) undertake measures to ensure that the use of narcotic drugs and psychotropic substances are limited to medical and scientific purposes;

(v) conduct research and studies on medical products and publish findings;

(w) build cooperation and partnership for harmonisation of practices with national, regional and international bodies with similar functions;

(x) develop emergency use authorisation mechanisms to allow for the expedited approval of medical products in the event of a public health emergency;

(y) establish a quality management system covering its regulatory functions;

(z) advise the Board and other persons on matters relating to medical products; and

(aa) report to the Minister on the operation and administration of this Act, and ensure that the purposes and objects of this Act are being achieved.

Quality management system

8. The Authority shall establish a robust, well-functioning quality management system that

(a) contributes to systematic planning, control and improved quality in all processes in regulatory functions, ensuring a comprehensive approach; and

(b) includes the application of quality risk management principles.

Collaboration with other bodies

9. The Authority may collaborate with any other regulatory authority or institution and, without limiting the generality of this power, may

(a) request necessary information from, exchange information with, and receive information from, any such authority or institution in respect of

(i) matters of common interest; and

(ii) specific investigations; and

(b) enter into agreements to cooperate with any other regulatory authority or institution in order to achieve the objects of this Act.

Board

10.(1) The Authority shall have a board of directors to be known as the Barbados Medical Products Board.

(2) The *First Schedule* has effect with respect to the constitution of the Board and otherwise in relation thereto.

(3) The Board shall be responsible for the strategic direction and governance of the Authority.

(4) Without prejudice to the generality of subsection (3), the Board shall be responsible for

(a) approving strategic plans and annual action plans of the Authority;

(b) providing strategic guidance to be followed in the fulfilment of the Authority's mission;

(c) setting policies of the Authority;

(d) providing oversight of the Authority's functions including the implementation of policies and the performance of the Authority;

(e) approving internal rules of the Authority;

(f) approving the budget of the Authority and monitoring its execution;

(g) approving the organisational structure of the Authority;

(h) approving mid-term activity reports, annual activity reports and financial reports of the Authority.

Remuneration of directors

11. The directors of the Board are entitled to such remuneration and allowances as the Minister determines.

Chief Executive Officer

12.(1) The Board shall, after consultation with the Minister, appoint a person to be the Chief Executive Officer of the Authority.

(2) The Chief Executive Officer shall hold office for a term of 3 years and is eligible for reappointment.

(3) The Chief Executive Officer shall be responsible for

(a) the day-to-day management and administration of the Authority, and the coordination and direction of its activities;

(b) preparing and implementing strategic and action plans for the Authority;

(c) preparing draft budget proposals for the Authority;

(d) preparing draft by laws, rules and guidelines of the Authority;

(e) managing the staff of the Authority;

(f) collecting and receiving promptly the revenues of the Authority;

(g) controlling, accounting for and reporting in a timely manner on, the revenue and expenditure of the Authority;

(h) managing the assets and liabilities of the Authority;

(i) achieving the level of performance required in the approved annual budget and the annual plan, and the statement of corporate intent of the Authority;

(j) ensuring that the decisions of the Board are implemented;

(k) producing the annual activity and financial reports of the Authority;

(l) preparing any other plans, budgets and reports required by any other enactment in respect of the Authority;

(m) performing such other functions relating to the mission of the Authority as the Board may assign; and

(n) performing such other functions as may be necessary to carry out the provisions of this Act.

(4) The Chief Executive Officer may delegate any of his functions to the Deputy Chief Executive Officer or an officer of the Authority but shall not be relieved of the ultimate responsibility for the performance of the delegated function.

(5) Subject to approval of the Minister, the Chief Executive Officer shall receive such salaries and allowances as the Board determines.

Other staff of Authority

13.(1) The Authority may appoint and employ such number of other officers and agents, including a Deputy Chief Executive Officer, as it considers necessary for giving effect to this Act at such remuneration and on such terms and conditions as the Minister approves in writing.

(2) The Authority may establish such divisions and separate its operations into such divisions, as it considers necessary for giving effect to this Act.

(3) The Authority may require any officer or division of the Authority to perform any of its functions.

Employment of public officers

14.(1) Where a public officer accepts employment with the Authority, he shall be employed on terms and conditions no less favourable than those to which he was entitled prior to his employment with the Authority.

(2) Where a public officer is seconded or temporarily transferred from a pensionable office within the meaning of section 2(1) of the *Pensions Act*, Cap. 25, to perform any service with the Authority, his service with the Authority shall, unless the President otherwise decides, count for pension under that Act as if the officer had not been so seconded or transferred.

(3) Where the services of a person employed by the Authority are on loan to the Government that person is entitled to such benefits and terms of employment as are applicable to the post which he occupies, and the service with the Authority shall be taken into account as continuous service with the Government and the *Pensions Act*, and the *Pensions Regulations, 1947* (1947-20) shall apply to him as if his service with the Authority were service within the meaning of that Act.

(4) Where a public officer is transferred to the service of the Authority in accordance with subsection (2), the Authority shall refund to the Consolidated

Fund all monies payable as pension in respect of the service of that officer with the Authority.

(5) Where a public officer who has pensionable service is transferred to or becomes employed in the service of the Authority, his service with the Authority shall, whether or not there was a break in service, be aggregated with his service in the public service and his pension shall be calculated in accordance with the *Pensions Act* and the *Pensions Regulations, 1947* as if all of his service was service in the public service.

Appointment of committees

15.(1) The Board may appoint committees to assist with the proper discharge of its functions subject to such conditions or restrictions as the Board imposes.

(2) The number of members of a committee appointed by the Board and the terms of office of the members shall be fixed by the Board.

(3) The Board may, with the approval of the Minister, determine the remuneration and allowances to be paid to the members of a committee.

(4) A committee appointed by the Board under this section may include persons who are not directors; but such persons shall not comprise more than one third of the membership of the committee.

(5) Notwithstanding the generality of subsection (1) to (4), the Board shall appoint a National Ethics Committee which shall be responsible for recommending the clearance of clinical trials of medical products in humans subject to the authorisation of the Authority.

(6) The membership, terms and conditions and remuneration of the National Ethics Committee appointed under subsection (5) shall be determined by the Board with the approval of the Minister.

Disclosure of interests

16. A director who has any interest in any matter or concern with which the Board proposes to make a decision shall disclose to the Board the fact of the interest and the nature of it and

(a) the disclosure shall be recorded in the minutes of the Board; and

(b) the Director shall not take part in any deliberation or discussion of the Board relating to such decision or vote thereon.

Funds of Authority

17. The funds of the Authority shall comprise

(a) such amounts as may be voted for the purpose by Parliament;

(b) all amounts payable to or vested in the Authority; and

(c) other funds legally obtained by the Authority.

Application of funds

18. The Authority shall apply its funds to

(a) the payment of its officers and employees;

(b) the discharge of its functions;

(c) the publication and promotion of its activities;

(d) the support of national, international, scientific and professional organisations, and the payment of annual and other contributions to such bodies; and

(e) such other purposes as are necessary for the performance of its functions.

Accounts

19. The Authority shall keep proper books of account of its revenues, expenditures, assets and liabilities and implement International Accounting Standards and Accounting Practices in accordance with the accounting standards and standing instructions issued by the Accountant General under the *Public Finance Management Act, 2019* (Act 2019-1).

Financial reports

20. The Authority shall submit such reports and information as required by Part IX of the *Public Finance Management Act, 2019* (Act 2019-1).

PART III

PHARMACY PREMISES

Certification of premises

21.(1) No person shall, whether on his own behalf or on behalf of another person, operate a pharmacy on any premises unless

(a) the Authority has certified the premises as being suitable for operating a pharmacy;

(b) the premises have been registered for the purpose of operating a pharmacy; and

(c) the pharmacy operated on the premises is under the immediate control, management and supervision of a pharmacist.

(2) A person may apply for certification of premises by

(a) submitting to the Authority an application in such form as the Authority determines; and

(b) paying the prescribed fee.

(3) Where the Authority approves the application, the Authority may, upon payment of the prescribed fee, issue a certificate of approval in respect of the premises.

(4) The certificate of approval

(a) shall be in such form as the Authority determines;

(b) is not transferable;

(c) is valid until the 31st day of December in the 3rd year from the date on which it was issued; and

(d) may be renewed during the month of January following its expiry, for further periods of 3 years where the Authority is satisfied that the premises remain suitable for operating a pharmacy.

(5) Where a pharmacy is in operation at the date of the commencement of this Act, application for certification must be made within 6 weeks from that date.

(6) A person who contravenes subsection (1) is liable to pay to the Authority an administrative penalty of $5 000 in accordance with Part XII.

Certificate of registration

22. The Chief Executive Officer shall, where he issues a certificate of approval under section 21

(a) register the premises for the purpose of operating a pharmacy; and

(b) issue a certificate of registration in respect of the premises.

Certificate of registration to be exhibited

23.(1) No person shall carry on the business of a pharmacy unless there is conspicuously exhibited in the pharmacy

(a) a certificate of registration issued under section 22 in respect of the pharmacy; and

(b) a valid certificate of registration of the pharmacist in charge of the pharmacy and of every pharmacist on duty therein as set out under section 4 of the *Pharmacy Act*, Cap. 372D.

(2) A person who contravenes subsection (1) is liable to pay to the Authority an administrative penalty of $5 000 in accordance with Part XII.

Cancellation and suspension of certificate of registration

24.(1) The Authority may cancel or suspend a certificate of registration where

(a) a pharmacy is no longer operated on the premises to which the certificate relates;

(b) the pharmacy that is operated on the premises to which the certificate relates, or any part of the pharmacy, including any fixture or cupboard, is in such a state of disrepair or insanitary condition as to render it likely that the pharmacy is not in compliance with the requirements of this Act.

(2) Where a pharmacy is no longer operated on the premises, the holder of the certificate to which the premises relate shall, within 7 days from the cessation of operations, deliver up the certificate to the Authority for cancellation.

(3) The Authority may, before cancelling or suspending a certificate under subsection (1)*(b)*, cause a notice to be served on the holder of the certificate requiring him to effect repairs or improvements of such nature, and by such date, as is specified in the notice.

(4) Subject to subsection (5), where repairs or improvements specified in a notice served under subsection (3) are not effected by the date stated in the notice or within such extended period as the Authority may grant, the Authority may cancel or suspend the certificate.

(5) The Authority shall not cancel or suspend a certificate without giving the holder of the certificate an opportunity to be heard as to why the certificate should not be cancelled or suspended.

(6) The holder of, a certificate that has been cancelled or suspended shall, after the cancellation or suspension, deliver it to the Authority without delay and the Chief Executive Officer shall remove the pharmacy located on those premises from the Register of Pharmacies.

Dispensing section of pharmacy

25.(1) A person who operates a pharmacy shall not permit the dispensing section thereof to be open unless

(a) a pharmacist is in charge thereof and in actual attendance therein; or

(b) all drugs in the dispensing section of the pharmacy required by this Act to be compounded, dispensed, stored for sale or retailed under the supervision of a pharmacist are in a cupboard or other place that is secure from public access.

(2) A person who contravenes subsection (1) is liable to pay to the Authority an administrative penalty of $5 000 in accordance with Part XII.

Register of Pharmacies

26. The Chief Executive Officer shall establish and maintain a register, to be known as the Register of Pharmacies, which shall contain

(a) the address and description of the premises in respect of which a certificate of approval is issued, and a copy of the certificate;

(b) a copy of the certificate of registration issued in respect of the premises; and

(c) the name, address and contact information of the person operating the pharmacy; and

(d) information on any suspension or cancellation of a certificate referred to in paragraph *(a)* or *(b)*; and

(e) such other information as the Chief Executive Officer considers necessary for the purposes of this Act.

PART IV

POISONS

List of poisons

27. The Authority shall, as soon as practicable after the commencement of this Act, publish in the *Official Gazette* a list of the names of the poisons, in relation to the storing for sale of which the exemption contained in section 29(1) applies.

Sale of poisons

28.(1) No person shall carry on a business that includes the selling by retail of a poison unless the business is carried out on premises registered for the purpose of operating a pharmacy or is operated by a person registered as an authorised seller of poisons.

(2) A person may apply for registration as an authorised seller of poisons by

(a) submitting to the Authority application in such form as the Authority determines; and

(b) paying the prescribed fee,

and the Authority may grant or refuse registration.

(3) Every person whose business includes the selling of a poison by retail shall keep the poison

(a) in a bottle, vessel, box, wrapper or cover

(i) distinctly labelled with the name of the poison; and

(ii) bearing a distinctive mark that it is a poison; and

(b) in an area set apart exclusively for the keeping of poisons.

(4) Subject to this Act, the *Sale of Poisons Act*, Cap. 151 extends to every sale of a poison under this Act.

(5) A person who contravenes subsection (1) or (3) is liable to pay to the Authority an administrative penalty of $5 000 in accordance with Part XII.

Exemptions

29.(1) Sections 21(1)*(a)* and 28 do not apply to premises maintained exclusively for the storage of drugs or poisons.

(2) Nothing in section 28, 34 or 35 shall be construed as applying to

(a) a drug

(i) administered or supplied by a medical practitioner to his patient;

(ii) administered by a midwife acting under regulation 18 of the *Nurses and Midwives (Registration) Rules, 1973* (S.I. 1973 No. 116);

(iii) administered by a nurse or midwife acting under the direction of a medical practitioner;

(iv) administered or supplied by a dental practitioner to his patient;

(v) administered or supplied by a veterinary practitioner for any animal under his care;

(vi) otherwise for the purpose of medical, dental or veterinary treatment, as the case may be;

(b) the sale of a drug

(i) to a medical practitioner, dental practitioner, or veterinary practitioner for the purpose of his profession;

(ii) to, or for use in connection with, any hospital; or

(iii) to a pharmacist for the purpose of a pharmacy or to a licensed distributor who has a pharmacist in his employment.

Use of titles

30.(1) No person shall, unless he is registered as a pharmacist, display on any premises any sign, title, emblem or representation that includes the description "drug store", "drug dispensary" or "pharmacy" or any other sign, title, emblem or representation that implies, or from which the public may reasonably infer, that those premises are registered as a pharmacy.

(2) A person who contravenes subsection (1) is liable to pay to the Authority an administrative penalty of $5 000 in accordance with Part XII.

PART V

CONTROL OF MEDICAL PRODUCTS

Licence to manufacture medical products for sale, distribution etc.

31.(1) Subject to section 39, no person shall manufacture for sale, distribution, or other supply any medical product unless he holds a licence to do so granted by the Authority.

(2) A person may apply for a licence to manufacture a medical product for sale, distribution or other supply by

(a) submitting to the Authority an application in such form as the Authority determines; and

(b) paying the prescribed fee.

(3) A person who contravenes subsection (1) is liable to pay to the Authority an administrative penalty of $15 000 in accordance with Part XII.

Licence to re-package or re-label medical products

32.(1) No person shall re-package, or re-label a medical product unless that person is the holder of a licence granted for the purpose by the Authority.

(2) A person may apply for a licence to re-package or re-label a medical product by

(a) submitting to the Authority an application in such form as the Authority determines; and

(b) paying the prescribed fee.

(3) A person who re-packages or re-labels a medical product shall comply with Good Manufacturing Practice standards to ensure the quality and safety of the medical product.

(4) A person who contravenes subsection (1) or (3) is liable to pay to the Authority an administrative penalty of $5 000 in accordance with Part XII.

Prohibitions on sale of certain medical products

33.(1) No person shall sell any medical product that is

(a) manufactured, prepared, preserved, packaged or stored for sale under insanitary conditions; or

(b) adulterated.

(2) A person who contravenes subsection (1) is liable to pay to the Authority an administrative penalty of $5 000 in accordance with Part XII.

Restriction on sale or supply of certain drugs

34.(1) No person shall sell or supply any drug, or substance or preparation containing any drug, contained in a list of drugs published in the *Official Gazette* by the Authority for the purpose of restricting such sale or supply, unless

(a) he is a practitioner or a person acting in accordance with the directions of such a practitioner, and the drug, substance or preparation is sold or supplied for the purpose of treating by, and in accordance with the directions of, the practitioner; or

(b) he is a pharmacist, and the drug, substance or preparation is sold or supplied under the authority of a prescription signed and dated by a practitioner referred to in paragraph *(a)*.

(2) The sale or supply of a drug, or substance or preparation containing a drug under subsection (1)*(a)* shall be limited to

(a) use in the office of a practitioner;

(b) an emergency; or

(c) a case that is special in nature by reason of a particular characteristic of a patient, such as age or infirmity, a medical condition or the drug involved,

and in any circumstance described in paragraph *(a)* to *(c)*, the supply shall not exceed 28 days' supply.

(3) Subsection (1) shall not apply to the sale or supply of a drug, or substance or preparation containing a drug, on a list referred to in that subsection

(a) by way of wholesale dealing;

(b) for the purpose of being exported;

(c) to a practitioner;

(d) to any authority or person in charge of the management of a hospital, clinic, nursing home or other institution providing medical, surgical, dental or veterinary treatment; or

(e) to a Ministry or a government department, agency or institution approved by the Authority for the purposes of this Act.

(4) A prescription signed by a practitioner authorising the sale or supply of any antimicrobial drug shall not, unless it expressly so directs, be dispensed on more than one occasion or more than 3 months after the date on which it was signed.

(5) Notwithstanding subsection (4), if the prescription expressly directs that it may be dispensed on a specified number of occasions or at specified intervals within a specified period it shall on the last time of dispensing be

(a) retained for a period of one year by the person last dispensing it; and

(b) made available for inspection by the Authority or by any person duly authorised by it to conduct inspections under this Act.

(6) A person who contravenes subsection (1) is liable to pay to the Authority an administrative penalty of $5 000 in accordance with Part XII.

Compounding or dispensing drugs

35.(1) No person shall compound or dispense drugs unless he complies with the following requirements:

(a) the compounding or dispensing of such drugs as are set out in a notice of the Authority, published in the *Official Gazette*, is done, in accordance with the notice, by

(i) a pharmacist; or

(ii) a graduate pharmacist or an intern pharmacist, under the supervision of a pharmacist on premises registered under this Act;

(b) all requirements relating to compounding or dispensing shall be complied with; and

(c) where the drug that is being compounded or dispensed is a poison section 28(3) and (4) shall be complied with.

(2) A person who contravenes subsection (1) is liable to pay to the Authority an administrative penalty of $5 000 in accordance with Part XII.

(3) For the purposes of subsection (l)*(a)*,

"graduate pharmacist" means a person who has completed the required course in the compounding, dispensing, selling and distribution of drugs, medicines, chemicals and poisons, but who has not completed his internship;

"intern pharmacist" means a graduate pharmacist who is undergoing internship;

"internship" means a period of practical training a graduate pharmacist must undergo before he is eligible for registration as a pharmacist.

Standard for drug in a publication

36.(1) Where a standard for a drug is contained in

(a) The British Pharmacopoeia;

(b) The European Pharmacopoeia;

(c) Martindale: The Complete Drug Reference;

(d) The Pharmacopoeia of the United States of America;

(e) The International Pharmacopoeia;

(f) Indian Pharmacopoeia; and

(g) Chinese Pharmacopoeia (English Version)

no person shall import, label, package or sell any substance in such a manner that it is likely to be mistaken for such drug unless the substance complies with most recent version of the official standard.

(2) The Minister may, after consultation with the Authority, by order amend the list in subsection (1).

(3) A person who contravenes subsection (1) is liable to pay to the Authority an administrative penalty of $5 000 in accordance with Part XII.

Licence to import drugs

37.(1) No person shall import a drug into Barbados unless

(a) he holds a licence to import such drug granted by the Authority;

(b) the drug has been manufactured by a pharmaceutical firm approved by the Authority; and

(c) the drug complies with such standard of strength, quality and purity as may be prescribed.

(2) A person may apply for a licence to import a drug into Barbados by

(a) submitting to the Authority an application in such form as the Authority determines; and

(b) paying the prescribed fee.

(3) A person who contravenes subsection (1) is liable to pay to the Authority an administrative penalty of $5 000 in accordance with Part XII.

Restriction on sale of drugs by importers

38.(1) No importer of a drug shall sell or transfer the drug to any person other than

(a) a medical practitioner;

(b) a dental practitioner;

(c) a veterinary surgeon; or

(d) a pharmacist,

unless the person holds a licence to store the drug granted by the Authority.

(2) A person who contravenes subsection (1) is liable to pay to the Authority an administrative penalty of $5 000 in accordance with Part XII.

Licence to store drugs

39.(1) No person shall store a drug for the purpose of sale unless he holds a licence to store the drug granted by the Authority.

(2) A person may apply for a licence to store a drug by

(a) submitting to the Authority an application in such form as the Authority determines; and

(b) paying the prescribed fee.

(3) The Authority shall not grant a licence described in subsection (1) unless it is satisfied that the storage facilities of the applicant are adequate.

(4) A person who contravenes subsection (1) is liable to pay to the Authority an administrative penalty of $5 000 in accordance with Part XII.

Licence to export drugs

40.(1) No person shall export a drug unless he holds a licence to export the drug granted by the Authority.

(2) A person may apply for a licence to export a drug by

(a) submitting to the Authority an application in such form as the Authority determines; and

(b) paying the prescribed fee.

(3) A person who contravenes subsection (1) is liable to pay to the Authority an administrative penalty of $5 000 in accordance with Part XII.

Manufacturing biological medical products and national lot release

41.(1) No person shall engage in the business of manufacturing or producing for sale any biological medical product unless

(a) he holds a licence to do so granted by the Authority;

(b) the process of manufacturing or producing the biological medical product is in all its stages under the direction and supervision of a qualified technical person with knowledge of biologic manufacturing processes; and

(c) each batch of the biological medical product manufactured or produced is numbered, and a sample of each batch is submitted to an analyst for such analysis and assay as the Authority may approve;

(2) Where medical products are imported from a country with which Barbados has a mutual recognition agreement confirming Good Manufacturing

Practice equivalence, the Authority may rely on official control batch release conducted in the exporting country and may waive duplicative testing.

(3) A person may apply for a licence to manufacture or produce a biological medical product for sale by

(a) submitting to the Authority an application in such form as the Authority determines; and

(b) paying the prescribed fee.

(4) A person who contravenes subsection (1) is liable to pay to the Authority an administrative penalty of $5 000 in accordance with Part XII.

Cancellation or suspension of licence issued under Part V

42. The Authority may cancel or suspend for such period as the Authority thinks fit any licence granted under this Part where the holder of the licence fails to comply with

(a) a provision of this Act or a statutory instrument made hereunder; or

(b) a condition in the licence.

PART VI

MARKETING AUTHORISATION AND REGISTRATION OF MEDICAL PRODUCTS

Registration and marketing authorisation

43.(1) No person shall import, manufacture, advertise, distribute, sell or offer for sale, or otherwise place on the market, a medical product unless the product has been registered and granted marketing authorisation by the Authority.

(2) Notwithstanding subsection (1), the Authority may by order exempt a medical product or category of medical products or part of any class or category of medical products from the requirement for marketing authorisation.

(3) Where a medical product was available for sale prior to the commencement of this Act, subsection (1) shall only apply to the medical product where no application for registration and marketing authorisation of the medical product is made within the period of 12 months immediately succeeding that date, on the expiration of that period.

(4) Subsection (1) shall not apply to the sale of a medical product compounded by a pharmacist for a particular patient, in the course of carrying out professional activities, in a quantity not greater than the quantity required for treatment as determined by a practitioner or a pharmacist, where

(a) the medical product does not contain a component

(i) the sale of which is prohibited by any law; or

(ii) in respect of which an application for marketing authorisation has been rejected; and

(b) the active component of the medical product appears in another medical product in relation to which marketing authorisation has been granted by the Authority.

(5) A person who contravenes subsection (1) is liable to pay to the Authority an administrative penalty of $5 000 in accordance with Part XII.

Application for registration and marketing authorisation

44.(1) A person may apply for registration and marketing authorisation in respect of a medical product by

(a) submitting to the Authority

(i) an application in such form as the Authority determines;

(ii) the samples requested by the Authority in respect of the medical product;

(iii) the technical qualifications of the applicant in relation to the medical product; and

(iv) such other information as the Authority considers necessary; and

(b) paying the prescribed fee.

(2) The Authority may determine

(a) the standards appropriate for new medical product, new uses, dosages, and formulations of existing medical products; interchangeable multi-source medicines, otherwise known as generic equivalents, and such other categories as may be appropriate; and

(b) standards and procedures for referencing, relying upon or otherwise weighing, the marketing assessments and other assessment mechanisms, and approvals of medical products regulatory authorities in other jurisdictions.

(3) The Authority shall grant registration and marketing authorisation in respect of a medical product where it is satisfied that

(a) the medical product is suitable for the intended purpose in respect of its quality, safety and efficacy; and

(b) the registration and marketing authorisation is in the public interest.

(4) Where the Authority intends to refuse to register a medical product and grant marketing authorisation in respect of it, the Authority shall

(a) notify the applicant in writing of the reasons for the refusal; and

(b) give the applicant one month from the date of the notification to object to the refusal and provide reasons for the objection.

(5) The Authority may refuse to register a medical product and grant marketing authorisation in respect of it where

(a) the applicant does not object to the refusal within the period stated in subsection (4); or

(b) after consideration of the objection of the applicant, and the reasons for it, the Authority is satisfied that the refusal is merited.

(6) The Authority shall publish the list of medical products approved for marketing authorisation in the *Official Gazette* and on the official website of the Authority.

Accelerated registration of medical products

45.(1) An accelerated registration procedure applies, in accordance with subsections (2) and (3), to a medical product approved by a stringent regulatory authority in another jurisdiction that is on the list approved and published by the Authority in accordance with section 57.

(2) Where the Authority, upon receipt of an application for registration of a medical product under section 44, determines that the same medical product is registered in another jurisdiction which is on the list of stringent regulatory authorities referred to in subsection (1)

(a) the application shall not be considered; and

(b) the applicant shall be advised to submit his case under the mutual recognition procedure.

Parallel import of medical products

46.(1) Where a medical product is not registered in Barbados, the Authority may register the medical product for parallel import where it is identical to a medical product registered in Barbados or sufficiently similar to it.

(2) A medical product shall be considered sufficiently similar to a medical product registered in Barbados if it meets the following criteria:

(a) the same active substance and the same salt thereof, the same ester, ether, isomer, mixture of isomers, complex or derivative;

(b) the same strength;

(c) the same pharmaceutical form and route of administration; and

(d) the same clinical properties.

(3) Where a medical product to be parallel imported is a generic product, it must be bioequivalent to the reference medical product registered in Barbados and, where it is compared with a generic product registered in Barbados, both products must be bioequivalent to the same reference product.

(4) The Authority shall maintain a list, to be known as the List of Parallel Imported Medical Products, of the medical products registered pursuant to subsection (1).

(5) A medical product on the List of Parallel Imported Medical Products may be parallel imported into Barbados where a parallel import permit has been issued in respect of the product by the Authority.

(6) A person may apply for a parallel import permit by

(a) submitting to the Authority

(i) an application in such form as the Authority determines; and

(ii) such other information as the Authority considers necessary; and

(b) paying the prescribed fee.

(7) The Authority may

(a) issue a parallel import permit upon such terms and conditions as it considers fit;

(b) approve changes to the terms and conditions of a parallel import permit; and

(c) suspend or revoke a parallel permit, after giving the holder of the permit, within 28 days of the date of receipt of a notice to suspend or revoke a parallel permit, an opportunity to be heard as to why the permit should not be suspended or revoked.

(8) A parallel import permit for a medical product shall be issued only to a legal entity that holds a wholesale distribution licence.

Supply of medicines in emergency situations

47. The Chief Executive Officer may, after consultation with experts in the scientific community, temporarily permit the supply to the market and the use of an unregistered medical product necessary for healthcare, and prescribe or recommend the use of a medical product without complying with the conditions of registration of the medical product, if the therapeutic indications, dosage or course of treatment indicated or recommended, as the case may be, are scientifically justified, where

(a) the presence of pathogenic or chemical agents, toxins or ionizing radiation hazardous to health is suspected or detected;

(b) a state of emergency or of war is declared; or

(c) any other emergency exists,

on a scale or in circumstances sufficient to justify permitting such supply and use in the market or prescribing or recommending such use.

Control of promotion and advertisement of medical products

48.(1) The promotion and advertisement of a medical product are subject to approval by the Authority.

(2) A person may apply for approval to promote or advertise a medical product by

(a) submitting to the Authority an application in such form as the Authority determines; and

(b) paying the prescribed fee.

(3) The Authority may issue

(a) guidelines relating to the promotion and advertising of medical products; and

(b) a Code of Marketing Practice.

(4) A person who

(a) promotes or advertises a medical product without the approval of the Authority; or

(b) contravenes a guideline or the Code of Marketing Practice issued under subsection (3)

is liable to pay to the Authority an administrative penalty of $5 000 in accordance with Part XII.

Prohibited advertisement

49.(1) No person shall

(a) advertise a medical product for any indication, use, treatment, prevention or cure for off-label or non-evidence-based use; or

(b) sell a medical product that is represented, whether by label, packaging, promotional material or advertisement or otherwise, as being suitable for any indication, use, treatment, prevention, or cure that is off-label or non-evidence-based use.

(2) A person who contravenes subsection (1) is liable to pay to the Authority an administrative penalty of $5 000 in accordance with Part XII.

Medical devices

50.(1) The Authority may use reliance and recognition tools developed by approved, stringent regulatory authorities and the International Medical Device Regulators Forum.

(2) The Authority may rely on unique device identification numbers of members of the International Medical Device Regulators Forum.

(3) The Authority may use a multi-tier system of approval of medical devices with considerations for intended use and risk to the patient based on 4 main pillars.

(4) The 4 main pillars for regulating medical devices are:

(a) risk classification;

(b) conformity or pre-market review which includes

(i) evidence of safety and performance;

(ii) technical documentation demonstrating compliance with essential principles of safety and performance, consistent with internationally recognised standards;

(iii) design dossier;

(iv) licence applications;

(c) quality management;

(d) post-market vigilance.

PART VII

POST-MARKETING SURVEILLANCE AND SAFETY MONITORING

Pharmacovigilance

51.(1) The Authority shall establish a National Pharmacovigilance Programme in order to monitor and report on the safety of medical products.

(2) The National Pharmacovigilance Programme established under subsection (1) shall facilitate

(a) monitoring and analysis of adverse effects or events relating to medical products;

(b) identifying and reporting adverse events relating to clinical trials;

(c) establishing causality, taking remedial actions, and reporting to international safety monitoring systems;

(d) appropriate regulatory action where necessary, including revising the marketing authorisation, labelling or warning requirements of the medical products.

Quality monitoring

52.(1) The Authority may institute a risk-based testing scheme consisting of sampling of medical products throughout the supply chain, to identify the products most at risk or likely to be falsified or substandard.

(2) The Authority may give directions in relation to medical products identified pursuant to subsection (1).

(3) A person who fails to comply with a direction given under subsection (2) is liable to pay to the Authority an administrative penalty of $5 000 in accordance with Part XII.

Recall and withdrawal

53.(1) Where the Chief Executive Officer finds that a medical product does not conform with the standards of identity, strength, quality and purity, or any other requirement specified in the documentation for registration, the Chief Executive Officer shall

(a) direct any person to discontinue the sale of the remainder of the batch of the medical product; and

(b) so far as is practicable, recall any portion of the batch already sold.

(2) The Authority may withdraw and strike a medical product from any register established under this Act where based on the latest available scientific evidence, the medical product is shown to be hazardous to public health and welfare, or unsafe, inefficacious or of an unacceptable quality.

(3) Where the Authority directs that the sale of a medical product be discontinued, recalls a medical product or withdraws and strikes a medical

product from a register, the Authority shall publish notice of its action and the medical product to which it relates

(a) in the *Official Gazette*;

(b) on its website; and

(c) by any other means, including the use of electronic media, likely to draw the notice to the attention of the public.

Withdrawal and disposal of medical products

54.(1) Where the Authority determines that it is not in the public interest that a medical product be made available to the public, the Authority may direct that the medical product be withdrawn from the market and disposed of in a manner prescribed.

(2) Section 53(3) applies with such modifications as may be necessary to a withdrawal of a medical product from the market under this section.

PART VIII

CLINICAL TRIALS AND NATIONAL QUALITY CONTROL LABORATORY

Control of clinical trials

55.(1) No person shall conduct a clinical trial of a medical product on humans without the clearance of the National Ethics Committee appointed pursuant to section 15 and the authorisation of the Authority.

(2) A person who seeks to conduct a clinical trial of a medical product on humans shall apply to the Authority for authorisation by

(a) submitting to the Authority an application in such form as the Authority determines; and

(b) paying the prescribed fee.

(3) All clinical trials shall be conducted in accordance with regulations made under this Act generally and, in particular, for Good Clinical Practice and Good Laboratory Practice.

(4) A person shall not sell, dispense, supply, assemble or manufacture a medical product for the purpose of a clinical trial or medical research on the product unless the person is authorised to do so or has been granted an exemption by the Authority in writing.

(5) The Authority shall establish and maintain a register of all clinical trials that it authorises under subsection (1).

(6) A person who contravenes subsection (1) is liable to pay to the Authority an administrative penalty of $5 000 in accordance with Part XII.

National Quality Control Laboratory and other laboratories

56.(1) There shall be established a laboratory to be known as the National Quality Control Laboratory which shall operate as part of the Authority.

(2) The National Quality Control Laboratory shall:

(a) analyse medical products;

(b) conduct research and training related to medical products; and

(c) undertake such other functions as the Authority determines.

(3) The Authority may, in performing its functions which require a laboratory, utilise any accredited laboratory within or outside Barbados to conduct the analysis of a medical product and undertake any related function.

(4) The National Quality Control Laboratory may recognise and rely on laboratory decisions, data and information from stringent regulatory authorities on the list referred to in section 57(1).

PART IX

RELIANCE AND INTERNATIONAL COOPERATION

Regulatory reliance on stringent authorities in other jurisdictions

57.(1) The Authority may, in performing its functions in respect of medical products, rely on stringent regulatory authorities in other jurisdictions, a list of which shall be approved and published by the Authority for the purpose.

(2) The Authority shall, in determining the list of stringent regulatory authorities to be approved and published, take into account the World Health Organisation Listed Authority (WLA) list and regional cooperation initiatives.

(3) Regulatory reliance by the Authority on any assessments, decisions and other information provided by stringent regulatory authorities on the list referred to in subsection (1) may be

(a) unilateral or may be based on binding mutual agreements or international treaties; and

(b) applied throughout the life cycle of a medical product in all regulatory functions, including initial authorisation and registration of the medical product, clinical trials, vigilance and other post-authorisation activities.

(4) The Authority, within the scope and conditions established by this Act or any of its statutory instruments, in its established forms and methods and to the extent determined, recognises or takes into account the assessments, decisions and other information provided by stringent regulatory authorities.

International cooperation

58.(1) The Authority shall cooperate with regional and international medical product regulatory authorities.

(2) The Authority shall share with other agencies at the regional and international level pharmaceutical intelligence on medical products that pose public health risks.

(3) The Authority shall take appropriate measures to ensure effective bilateral, regional and international co-operation to combat the production, circulation and use of substandard, spurious, falsified, falsely labelled and counterfeit medical products, illicit drugs, narcotics and psychotropic substances.

Regulatory harmonisation initiatives

59.(1) The Authority shall participate in harmonisation initiatives of regional and international medical products regulatory authorities.

(2) Without prejudice to the generality of subsection (1), the Authority shall take measures to ensure effective cooperation with medical products regulatory authorities in other jurisdictions to

(a) harmonise registration of medical products, inspections, quality management systems, information management systems, joint evaluations, joint inspections and any other regulatory activities as may be appropriate;

(b) provide for the use of accredited quality control laboratories within a harmonisation framework;

(c) provide for the recognition of regional and international technical guidelines;

(d) provide for harmonisation of the data requirements for evidence of quality, safety, and efficacy of medical products, and the grounds on which authorisation for distribution shall be granted within the region;

(e) provide for mutual recognition of marketing authorisation decisions;

(f) share summary evaluation and inspection reports;

(g) participate in common post-marketing surveillance conducted in accordance with nationally and internationally recognised standards;

(h) strengthen national regulatory capacity;

(i) establish networks and collaborate in protecting public health through enforcement activities;

(j) establish exchange programmes so as to keep abreast of evolving scientific development in the field of medical products; and

(k) provide for transparency and information sharing through

(i) the establishment of a quality management system based on common regional and international requirements to ensure efficiency;

(ii) the creation of a national information management system to allow for sharing information at regional and international levels in accordance with national laws and bilateral and multilateral agreements.

PART X

INSPECTION

Inspection

60.(1) The Authority may appoint inspectors for the purposes of this Act.

(2) An inspector may enter any premises

(a) in respect of which an application to the Authority under this Act has been made;

(b) on which a pharmacy is being operated;

(c) on which medical products or poisons are being sold retail or wholesale;

(d) where medical products are being manufactured or packaged; or

(e) in respect of which there are reasonable grounds to believe that this Act is being contravened,

and conduct an inspection to determine whether the premises or any medical product thereon or any person, in relation to the premises or product, satisfies or is in compliance with the requirements of this Act.

(2) The Authority shall issue an inspector with a certificate of identity, in such form as determined by the Authority; and the inspector shall, if required to do so by the occupier of premises, produce the certificate of identification on entering the premises for the purposes of subsection (2).

(3) An inspector may, in conducting an inspection

(a) take photographs;

(b) take samples; and

(c) examine any books, electronic devices, documents or other records which he reasonably believes contains any information relevant to the requirements of this Act, and make copies thereof or take extracts therefrom; and

(d) seize and detain for a period not exceeding 6 months, any article by means of or in relation to which he reasonably believes any provision of this Act has been contravened.

(4) An occupier of premises shall give to an inspector entering the premises such assistance as the inspector may require.

(5) For the avoidance of doubt, nothing in this section operates to prevent an inspector from entering and inspecting the premises of a practitioner or any premises where he has reason to believe that the dispensing or distribution of a medical product is being carried out on the premises.

Evidence in relation to samples

61.(1) Subject to subsection (2), a certificate signed by an inspector or by a person acting in the performance of his functions as an analyst under any law

affecting public health, stating that he has examined or analysed a sample taken under section 60 and stating the result of the examination or analysis, is *prima facie* evidence of everything contained in the certificate including the signature and the qualification of the person signing the certificate.

(2) A certificate of an inspector or analyst is not admissible in evidence unless the person who took the sample

(a) divided the sample into 2 parts and gave one part of it to the person from whom it was taken; and

(b) not less than 2 weeks before any proceedings in court to which the sample relates

(i) gave notice in writing to the person from whom the sample was taken of his intention to produce the certificate in evidence; and

(ii) served on that person a copy of that certificate.

PART XI

APPEALS

Establishment of the Barbados Medical Products Appeals Tribunal

62.(1) There is established a tribunal, to be known as the Barbados Medical Products Appeals Tribunal, which shall hear appeals from persons described in section 63.

(2) The Tribunal shall comprise

(a) an attorney-at-law of at least 10 years' standing;

(b) a medical practitioner, a veterinary surgeon and a pharmacist, each with at least 10 years' experience;

(c) a person with at least 10 years' experience in the area of medicine, pharmacy, nursing, veterinary medicine or public health, [at the discretion of the Minister.]

(3) The members of the Tribunal shall

(a) be appointed by the Minister by instrument in writing for a period of 3 years and are eligible for re-appointment; and

(b) receive such remuneration as the Minister responsible for Finance determines.

Appeal to Tribunal

63. A person who is aggrieved by a decision of the Chief Executive Officer or the Authority under this Act may, within 14 days of receipt of notice of the decision, appeal to the Tribunal.

Suspension of decisions pending appeal to Tribunal

64. The Chief Executive Officer or the Authority shall, pending an appeal to the Tribunal, on the application of the appellant, suspend the coming into effect of the decision that is the subject of the appeal until the appeal is determined.

Power of Tribunal

65. The Tribunal may

(a) dismiss an appeal and confirm the decision of the Chief Executive Officer or the Authority;

(b) allow the appeal and where applicable

(i) set aside the decision and grant such relief as the Tribunal thinks fit;

(ii) direct that the matter in respect of which the decision was made be further considered by the Chief Executive Officer or the Authority; and

(iii) set aside an administrative penalty and impose such other administrative penalty, if any, as the Tribunal thinks fit.

Appeal to High Court

66. A party to an appeal to the Tribunal may appeal from the decision of the Tribunal on a point of law to the High Court.

PART XII

ADMINISTRATIVE PENALTIES

Administrative penalty notice

67.(1) The Authority shall issue an administrative penalty notice in the form set out in the *Second Schedule* to a person where the Authority is satisfied that

(a) the person has contravened a provision of the Act; and

(b) the contravention renders the person liable to pay an administrative penalty.

(2) An administrative penalty notice shall

(a) specify the nature of the act constituting the contravention;

(b) state amount of the penalty to be paid; and

(c) require the person to whom it is addressed to pay the penalty within 30 days of the date of the notice.

(3) A person who is in receipt of an administrative penalty notice issued pursuant to subsection (1) shall pay the amount of the penalty set out in the notice on or before the date specified in the notice.

Procedure for challenging an alleged administrative contravention

68. Notwithstanding section 67, a person to whom an administrative penalty notice is addressed and who wishes to challenge the alleged contravention, may instead of paying the administrative penalty, appeal to the Tribunal.

Administrative penalty to constitute a debt to the State

69. The amount of an outstanding administrative penalty constitutes a debt to the State and is recoverable in civil proceedings before a magistrate for District 'A'.

PART XIII

OFFENCES

Offences relating to inspectors

70. Any person who

(a) assaults or obstructs an inspector in the performance of his functions;

(b) by the offer of any gratuity, bribe or other inducement prevents or attempts to prevent an inspector from performing his functions; or

(c) knowingly gives false information to an inspector in the performance of his functions or gives information that is likely to mislead an inspector in the performance of his functions

commits an offence and liable on summary conviction to a fine of $50 000 or to imprisonment for a term of 2 years or to both.

False, misleading or deceptive impressions

71.(1) No person shall manufacture, import, export, supply, store, distribute, sell or advertise any medical product in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

(2) A person who contravenes subsection (1) commits an offence and is liable on summary conviction to a fine of $50 000 or to imprisonment for a term of 2 years or to both.

False or misleading statements

72. A person who makes a false or misleading statement in connection with a medical product in the course of an application for

(a) marketing authorisation thereof; or

(b) a licence in respect thereof,

commits an offence and is liable on summary conviction to a fine of $50 000 or to imprisonment for a term of 2 years or to both.

Tampering

73. A person who with fraudulent intent, tampers with a sample taken in accordance with this Act commits an offence and is liable on summary conviction to a fine of $50 000 or to imprisonment for a term of 2 years or to both.

PART XIV

MISCELLANEOUS

Exemption from import duty, value added tax etc

74.(1) Notwithstanding any other enactment, the Authority is exempt from the payment of

(a) import duty and value added tax on any materials, reagents and articles, including equipment, imported or purchased out of a bonded warehouse for the use of the Authority in the discharge of its functions;

(b) property transfer tax and land tax; and

(c) stamp duty.

(2) The exemptions granted under subsection (1)*(a)* are subject to the condition that the Authority keeps and renders such accounts in respect of the use or disposal of the materials and articles as the Comptroller of Customs requires.

Regulations

75.(1) The Board may make regulations generally for the purpose of giving effect to this Act.

(2) Without prejudice to the generality of subsection (1), the Board may make regulations in particular in relation to the following:

(a) the standard of strength, quality and purity of any medical product to which this Act applies;

(b) the test to be used for determining whether such prescribed standard has been maintained;

(c) the conditions subject to which licences, certificate or registration may be issued or granted as the case may be;

(d) the exclusion from the operation of this Act or of any of the provisions of this Act, any drug or therapeutic substance intended to be used solely for veterinary purposes;

(e) the specification of the substances that are poisons for the purposes of this Act;

(f) providing for the registration of authorised sellers of poisons;

(g) providing for

(i) the compounding, dispensing, labelling, storing, packaging, re-packaging and re-labelling, sale and retailing of medical products and poisons;

(ii) the containers in which poisons are to be stored, sold or supplied; and

(iii) the addition to poisons of specified ingredients for the purpose of rendering them readily distinguishable as poisons;

(h) providing in respect of sellers of poisons for the keeping and examination of books, electronic devices and records and for the making of reports;

(i) prescribing those places, other than pharmacies, in which poisons included in the list referred to in section 27 may be stored for sale or may be sold by retail and the requirements to be satisfied in relation to the storing and retailing in those places of those poisons;

(j) registration, including accelerated registration of medical products, and the grant of marketing authorisation;

(k) the import and export of medical products including a list of pharmaceutical firms approved as manufacturing firms, from which medical products may be imported;

(l) the storage and transportation of medical products;

(m) the control or prohibition of any process which may affect the potency, sterility or toxicity of any medical product;

(n) the prices of medical products regulated by the Authority;

(o) the regulation of lot release;

(p) the recall, withdrawal from the market and disposal of medical products;

(q) the investigation and control of chemical precursors and substances used in the manufacture of narcotics and psychotropic drugs;

(r) post-marketing surveillance of regulated medical products;

(s) pharmacovigilance, including provision for mandatory reporting and the submission of periodic safety updates by manufacturers and distributors, and voluntary reporting by health care professionals and the public;

(t) clinical trials;

(u) Good Practices including, Good Manufacturing Practices, Good Distribution Practices and Good Pharmacy Practices;

(v) medicated cosmetics; and

(w) the charging of fees for services rendered by the Authority.

(3) For the purposes of subsection (2)*(g)*, different provisions may be prescribed in respect of different medical products or different poisons.

Guidelines and directives

76.(1) The Authority may issue guidelines and directives for the purpose of providing information and guidance in relation to compliance with this Act or any statutory instruments made under this Act.

(2) Without prejudice to the generality of subsection (1), the Authority may issue guidelines in respect of the re-packaging and re-labeling of any medical product.

Amendment of schedules

77. The Minister may by Order amend the *First* and *Second Schedules*.

Consequential amendments

78. The enactments set out in Column 1 of the *Third Schedule* are amended in the manner specified in Column 2.

Repeal and revocation

79.(1) The *Therapeutic Substances Act*, Cap. 330 is repealed.

(2) The *Health Services (Control of Drugs) Regulations, 1970* (S.I. 1970 No. 212) and the *Therapeutic Substances Regulations, 1950* are revoked.

Commencement

80. This Act shall come into operation on a date to be fixed by Proclamation.

FIRST SCHEDULE

(Section 10)

Constitution and Procedure of the Barbados Medical Products Board

Constitution of Board

1.(1) The Board shall comprise

(a) a Chairman;

(b) Deputy Chairman; and

(c) 7 other directors,

who are qualified and experienced in medicine, pharmaceuticals, business or any other relevant field, as the Minister may appoint by instrument in writing.

(2) A director

(a) holds office for such period, not exceeding 3 years, as the Minister determines unless he resigns or his appointment is revoked before the end of that period; and

(b) is, on the expiration of the period of his appointment, eligible for re-appointment for further periods not exceeding 3 years.

Temporary appointment

2. The Minister may, in accordance with paragraph 1, appoint a person to act temporarily in the place of a director who is absent from Barbados or is unable to act.

Resignation of Chairman, Deputy Chairman or other directors

3.(1) The Chairman or Deputy Chairman may at any time resign his office by instrument in writing addressed to the Minister and, upon the receipt by the Minister of the instrument, the Chairman or Deputy Chairman ceases to be

Chairman or Deputy Chairman and, if the instrument so specifies, also ceases to be a director of the Board.

(2) A director, other than the Chairman or Deputy Chairman, may at any time resign his office by instrument in writing addressed to the Minister and transmitted through the Chairman and, from the date of the receipt by the Minister of the instrument, the director ceases to be a director of the Board.

Absence from meetings

4. A director who fails, without reasonable excuse, to attend 3 consecutive meetings of the Board ceases to be a director and is not eligible for appointment to the Board until the expiry of 3 years from the date when he ceased to be a director.

Revocation of appointment

5. The Minister may at any time by instrument in writing revoke the appointment of a director.

Vacancy

6. Where a vacancy in the Board is created by the death, resignation or removal from office of a director or otherwise, the Minister may, in accordance with paragraph 1, appoint another a person to fill the vacancy.

Notice of appointments etc.

7. The appointment and the cessation of appointment of a director shall be notified in the *Official Gazette.*

Secretary

8. The Authority shall have a Secretary.

Seal

9.(1) The seal of the Authority shall be kept in the custody of the Chairman or Deputy Chairman, or such officer of the Board as the Board approves, and may be affixed to documents or instruments pursuant to a resolution of the Authority in the presence of the Chairman or Deputy Chairman and the Secretary.

(2) The seal of the Authority shall be authenticated by the signature of the Chairman and the Secretary.

(3) All documents or instruments, other than those required by law to be under seal, and all decisions of the Authority may be signified under the hand of the Chairman or Deputy Chairman.

Meetings

10. The Board shall meet at least once a month and at such other times as may be necessary or expedient for the transaction of its business.

Special meetings

11. The Chairman or, in the event of his absence from Barbados or inability to act as such, the Deputy Chairman, may at any time call a meeting of the Board and shall call a meeting within 7 days of receipt of

(a) a request for that purpose addressed to him in writing and signed by 3 other directors;

(b) a direction to that effect addressed to him in writing and signed by the Minister.

Presiding at meetings

12. The Chairman or, in his absence, the Deputy Chairman shall preside at all meetings of the Board and, in the case of the absence of both, the directors present and constituting a quorum shall elect a temporary Chairman from among their number who shall preside at the meeting.

Quorum

13. The majority of the directors of the Board shall constitute a quorum.

Decisions

14. The decisions of the Board shall be by a majority of votes and, in any case in which the voting is equal, the Chairman, the Deputy Chairman or the other director presiding at the meeting has, in addition to an original vote, a second or casting vote.

Minutes

15.(1) Minutes of each meeting shall be kept by the Secretary or such officer as the Board appoints for the purpose and shall be confirmed in writing at the next meeting by the Chairman or Deputy Chairman.

(2) Confirmed minutes of meetings shall be submitted to the Minister within one month of the date of the meeting at which they were confirmed.

Attendance of non-members at meetings

16.(1) The Chairman may invite any person to attend a meeting of the Board where the Board considers it necessary to do so.

(2) A person referred to in subparagraph (1) may take part in the deliberations of the Board but shall not vote on any matter.

Validity of decisions of Board

17. Any act done or proceeding conducted by the Board under this Act or any regulations made under this Act may not be questioned on the ground of

(a) the existence of any vacancy in the membership of, or defect in, the constitution of the Board;

(b) any omission, defect or irregularity that does not affect the merits of the case.

SECOND SCHEDULE

(Section 67)

Barbados Medical Products Authority Act, 2026
(Act 2026-)

Administrative Penalty Notice

To:_____

On the_____day of_____, 20_____, at_____
(Time)

at_____, it was observed that there was a
(Location)

contravention of the Act. The particulars of the contravention are set out as follows:

_____

_____

_____

_____

The sum of the administrative penalty to be paid: _____

Signature of the Chief Executive Officer: _____

Date:_____

THIRD SCHEDULE

(Section 78)

CONSEQUENTIAL AMENDMENTS

Column 1 *Enactments*	Column 2 *Amendments*
1. *Drug Abuse Prevention and Control Act,* Cap.131	1. In section 2, *(a)* delete the definition of "committee"; and *(b)* insert in alphabetical order, the following definition: " "Barbados Medical Products Authority" has the meaning assigned to it by the Barbados *Medical Products Authority Act 2026* (Act 2026-);". 2. In section 3(3) delete the word "Committee" and substitute the words "Barbados Medical Products Authority". 3. In section 12(6), delete the word "Committee" and substitute the words "Barbados Medical Products Authority".
2. *Food and Drugs Adulteration Act,* Cap. 327	1. In section 2 delete the definition of "drugs" and substitute the following: " "drugs" means any chemical substance that when consumed causes a change in an organism's physiology, including its psychology, where applicable;". 2. In section 14(1) insert after the words "Medical Officer of Health" the words, "officer of the Barbados Medical Products Authority,".

Third Schedule - (Cont'd)

CONSEQUENTIAL AMENDMENTS - *(Cont'd)*

Column 1	Column 2
Enactments	*Amendments*
3. *Pharmacy Act*, Cap. 372D	1. In section 2 *(a)* insert in alphabetical order the following: " "Barbados Medical Products Authority" has the meaning assigned to it by the Barbados *Medical Products Authority Act 2026* (Act 2026-);". *(b)* delete the definition of the word "inspector". 2. In section 11 *(a)* delete paragraph *(c)*; and *(b)* in paragraph *(d),* delete the words "other sellers of poisons". 3. Delete sections 15, 16, 17 and 18. 4. In section 25(1) *(a)* in paragraph *(b)*(iii), replace the semi-colon with a full stop; and (b) delete paragraphs *(c)* and *(d)*. 5. Delete sections 26, 27, 28, 29 and 30.

Third Schedule - (Cont'd)

CONSEQUENTIAL AMENDMENTS - *(Cont'd)*

Column 1	Column 2
Enactments	*Amendments*
3. *Pharmacy Act*, Cap. 372D - *(Cont'd)*	6. Delete section 31 and substitute the following: "**Use of titles** **31**. No person shall, unless he is registered as a pharmacist or any other authorised seller of poisons, as the case may be, make use of any of the following titles: *(a)* pharmacist; *(b)* druggist; *(c)* pharmaceutical chemist; *(d)* pharmaceutist; *(e)* dispenser; or *(f)* authorised seller of poisons.". 7. Section 32 and 33 are deleted.

Third Schedule - (Cont'd)

CONSEQUENTIAL AMENDMENTS - *(Cont'd)*

Column 1	Column 2
Enactments	*Amendments*
3. *Pharmacy Act*, Cap. 372D - *(Concl'd)*	8. Delete section 34 and substitute the following: "**Regulations** **34**. The Council may, with the approval of the Minister, make Regulations *(a)* respecting the manner in which disciplinary proceedings or enquiries are to be instituted and the procedure to be followed in the conduct of those proceedings or enquiries; *(b)* prescribing the qualifications necessary for registration as a pharmacist; *(c)* prescribing anything that is by this Act authorised or required to be prescribed.". 9. In section 35 *(a)* delete paragraphs *(a)*, *(b)* and *(c)*; *(b)* renumber paragraphs *(d)*, *(e)* and *(f)* as paragraphs *(a)*, *(b)* and *(c)* respectively. 10. Renumber the *First Schedule* as the *Schedule* and delete the words "*First Schedule*" wherever they appear in the Act and substitute the word "*Schedule*". 11. Delete the *Second Schedule.*

Third Schedule - (Cont'd)

CONSEQUENTIAL AMENDMENTS - *(Cont'd)*

Column 1	Column 2
Enactments	*Amendments*
4. *Public Finance Management Act, 2019* (Act 2019-1)	In the *First Schedule,* insert in alphabetical order the following: "Barbados Medical Products Authority".
5. *Statutory Boards (Pensions) Act*, Cap. 384	1. In the *First Schedule* insert in alphabetical order the following: "Barbados Medical Products Authority 1. Chief Executive Officer 2. Deputy Chief Executive Officer 3. Assistant Director 4. National Regulatory Officer 5. Director Market Authorisation/Drug Registration 6. Deputy Director Market Authorisation/ Drug Registration 7. Market Authorisation Officer 8. Drug Registration Officer 9. Director Pharmacovigilance 10. Deputy Director Pharmacovigilance 11. Pharmacovigilance Officer 12. Director Market Surveillance 13. Deputy Director Market Surveillance 14. Market Surveillance Officer 15. Director Licensing 16. Deputy Director Licensing

Third Schedule - (Concl'd)

CONSEQUENTIAL AMENDMENTS - *(Concl'd)*

Column 1	Column 2
Enactments	*Amendments*
5. *Statutory Boards (Pensions) Act*, Cap. 384 - *(Concl'd)*	17. Licensing Officer 18. Director Inspections 19. Deputy Director Inspections 20. Inspections Officer 21. Director Lab Testing 22. Deputy Director Lab Testing 23. Lab Testing Officer 24. Director Clinical Trials 25. Deputy Director Clinical Trials 26. Clinical Trials Officers 27. Human Resources Manager 28. Financial Controller 29. Accounts Assistant 30. Office Manager 31. Information and Systems Director 32. Legal Officer 33. Messenger 34. Maid".

2. In the *Second Schedule,* in alphabetical order insert the following:

"Barbados Medical Products Authority".

Read three times and passed the House of Assembly this day of , 2026.

Speaker

Read three times and passed the Senate this day of , 2026.

President

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