

A BILL

entitled

PHARMACY AND POISONS AMENDMENT ACT 2011

WHEREAS it is necessary to amend the Pharmacy and Poisons Act 1979 to strengthen the regulatory control over the importation of prescription medicines into Bermuda to ensure safety and quality;

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 2011.

Amends section 2

2 Section 2 of the principal Act is amended in the definition of "Schedule 3 drug" by deleting "25(4)" and substituting "25(6)".

Repeals section 25

3 Section 25 of the principal Act is repealed and replaced with the following—

"Restrictions on the importation of medicines

25 (1) A person shall only import into Bermuda for medicinal use medicines that are obtained from foreign manufacturers or foreign wholesalers if those medicines are eligible for sale in the United States of America, Canada or a country in the European Union in accordance with the regulatory standards of the relevant country.

(2) A person who acquires medicine from abroad for distribution or sale in Bermuda shall register with the Minister in accordance with regulations made under this Act by the Minister.

(3) Any person who fails to comply with this section or any regulations made under this Act commits an offence.

## PHARMACY AND POISONS AMENDMENT ACT 2011

---

(4) A person who fails to comply with this section or any regulations made under this Act may have any medicines being imported by him forfeited to the Crown.

(5) The Minister may make regulations to prescribe the requirements for—

(a) the registration of a person under subsection (2); and

(b) the importation of medicines.

(6) In this section—

“manufacturer” means a person involved in the production, preparation, propagation, conversion, processing, packaging or labelling of medicine;

“medicine” means any substance specified in the Third Schedule (in this Act referred to as a “Schedule 3 drug”);

“wholesaler” means a person who obtains medicine for distribution or delivery to persons other than consumers.

(7) The negative resolution procedure shall apply to regulations made under this section.”

### Repeals section 26

4 Section 26 of the principal Act is repealed.

### Amends Third Schedule

5 The Third Schedule is amended in the section reference by deleting “25(4)” and substituting “25(6)”.

### Revocation of BR 27/2009

6 The Pharmacy and Poisons (Designation of Approved Countries) Order 2011 is revoked.

## PHARMACY AND POISONS AMENDMENT BILL 2011

### EXPLANATORY MEMORANDUM

The purpose of this Bill is to amend the Pharmacy and Poisons Act 1979 (the “principal Act”) to strengthen the regulatory control over the importation of prescription medications into Bermuda, ensuring the quality of the medicine and the safety to the public.

Clause 1 provides the title of the Bill.

Clause 2 amends the definition of “Schedule 3 drug” by changing the section reference to reference the correct subsection in the new section 25.

Clause 3 replaces section 25 of the principal Act with new regulatory guidelines for the importation of medicines into Bermuda.

Subsection (1) provides that medicines can now only be imported into Bermuda if they are eligible for sale in the United States, Canada or a country in the European Union and if the manufacturers and wholesalers of the medicines comply with the regulatory standards of the relevant country.

Subsection (2) requires a person who imports drugs commercially (i.e. for distribution and sale) to register with the Minister according to the regulations made by the Minister. A person who imports medicines for personal use is not required to register under the Act. A person who is required to register and does not commits an offence under section 55 of the Act (punishable with 12 months imprisonment or a fine on summary conviction of \$5000, or 3 years imprisonment or a fine of \$15,000 on indictment).

Subsection (3) provides that a person importing drugs for either commercial or personal use who does not comply with section 25 or the regulations made under the Act by the Minister, commits an offence under section 55 of the Act (punishable with 12 months imprisonment or a fine on summary conviction of \$5000, or 3 years imprisonment or a fine of \$15,000 on indictment).

Subsection (4) provides that a person who does not comply with section 25 or any Regulation made under the Act may have the medicine they import forfeited to the Crown.

Subsection (5) gives the Minister the power to make regulations under the Act, subject to negative resolution procedure, prescribing the form of registration of persons who import drugs commercially and for the importation of Schedule 3 drugs into Bermuda.

Subsection (6) contains definitions included in the new section 25 to clarify the meanings of manufacturer, medicine and wholesaler.

## PHARMACY AND POISONS AMENDMENT BILL 2011

---

Subsection (7) provides that the negative resolution procedure applies to all regulations made under section 25.

Clause 4 repeals section 26 of the principal Act, which is superseded by the new section 25.

Clause 5 amends the section reference in the Third Schedule to cross reference the correct subsection in the new section 25.

Clause 6 revokes the Pharmacy and Poisons (Designation of Approved Countries) Order 2011.