AN ACT

To amend Sections 5.02 and 5.03 of Act No. 247 of September 3, 2004, as amended, known as the “Puerto Rico Pharmacy Act,” in order to require that in the event that the pharmacist interchanges the prescribed medication for another one, in accordance with the legislation in effect, the labeling of the dispensed product shall include the names of both medications together with the phrase “bioequivalent to” or a similar language indicating that the prescribed medication was interchanged, except when the prescribing professional indicates otherwise in writing.

STATEMENT OF MOTIVES

Act No. 247 of September 3, 2004, as amended, known as the “Puerto Rico Pharmacy Act,” was enacted to strengthen the Puerto Rico Board of Pharmacy, the body responsible for the regulation of the pharmacist profession, and to establish a more specific definition of the responsibilities and functions of the pharmacist and the pharmacy technician. Furthermore, this Act created the Medication and Pharmacy Division, as an administrative unit of the Department of Health, for a more effective monitoring of drug manufacture, distribution, and dispensing as well as their interchange for bioequivalent drugs in Puerto Rico.

Section 5.03 of the Puerto Rico Pharmacy Act authorizes the interchange of a prescribed medication for a bioequivalent one when the therapeutic equivalence of the latter has been recognized by the U.S. Food and Drug Administration (FDA) and the same is codified as such in the Approved Drug Products with Therapeutic Equivalence Evaluations, better known as the Orange Book. Act No. 247, supra, defines bioequivalent medications as “those drugs classified by the Food and Drugs Administration (FDA) as therapeutically equivalent since they contain the same active ingredients, have the same strength, dosage, and form of administration; and have comparable bioavailability.”
According to the legislation in effect, the medication interchange has to meet with each and every one of the following conditions: 1) the bioequivalent medication is included in the *Orange Book* under a codification starting with the letter “A”; 2) the same costs less than the prescribed medication. In the event that the prescribed medication or another at a lesser price is not available, an equally priced medication may be dispensed, if the patient or his/her representative agrees; and 3) the patient or his/her representative has given his/her consent to interchanging. The patient’s consent shall be documented with his/her signature on the back of the prescription sheet for each medication in particular.

The dispensation of medications by a pharmacist is a process that must be carefully carried out and requires all the potential safeguards to ensure the safety of the patient. This process includes the receipt, verification, evaluation, and interpretation of the prescription, the selection, packaging, labeling, and dispatch of the medication to the patient or its authorized representative, as well as orientation on the proper use for such medication.

One of the safeguards of Act No. 247 requires that when interchanging the medication, the pharmacist shall record in the patient’s pharmacy record or on the back of the prescription the date on which the medication is interchanged and he/she shall sign the prescription. Furthermore, the pharmacist shall also record on the back of the prescription the drug trade name or trademark of the medication thus dispensed. Should the medication not have trade name or trademark, the pharmacist shall record the generic name and the name of the manufacturer or distributor that appears on the medication’s label. However, for the benefit of the patient and as an additional measure, it is convenient to indicate on the label that the prescribed medication was substituted.
This Legislative Assembly deems it necessary and meritorious to amend Sections 5.02 and 5.03 of Act No. 247 of September 3, 2004, as amended, known as the “Puerto Rico Pharmacy Act,” in order to require that when the pharmacist interchanges a prescribed medication for another, in accordance with the legislation in effect, the labeling of the dispensed medication shall include the names of both medications together with the phrase “substitute for” or a similar language that indicates the substitution of the prescribed medication, except when the prescribing professional indicates otherwise in writing.

**BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF PUERTO RICO:**

Section 1.- Subsection (d) of Section 5.02 of Act No. 247 of September 3, 2004, as amended, is hereby amended to read as follows:

“Section 5.02.- Dispensation of Prescription Medications.-

(a) …

(d) The labeling of all medications dispensed by prescription shall contain, among other things, the following data: name of the pharmacy with its address and phone number; serial number assigned to the prescription; date of dispensation; name, potency, and indications for use of the medication; name and surname of the patient and the prescribing professional; and expiration date and lot number of the medication. In the event that the pharmacist interchanges the prescribed medication, pursuant to Section 5.03 of this Act, the labeling of the dispensed product shall include the names of both medications together with the phrase ‘bioequivalent to’ or a similar language indicating that the prescribed medication was interchanged, except when the prescribing professional indicates otherwise in writing.”

(n) …

(o) …
Section 2.- Paragraph (5) of subsection (b) of Section 5.03 of Act No. 247 of September 3, 2004, as amended, is hereby amended to read as follows:

“Section 5.03.- Interchange of Bioequivalent Medications.-

(a) …

(b) Pharmacist’s authority to interchange bioequivalent medications.— The pharmacist may interchange bioequivalent medications in the manner stated below:

(1) …

(A) …

(B) …

(C) …

(2) …

(3) …

(4) …

(5) The pharmacist shall label the product thus dispensed with the brand name or trademark in the event he/she has dispensed a brand name product, or with the generic name and the name of the manufacturer, in the event he/she has dispensed a generic product. In the event that the pharmacist interchanges the prescribed medication for another one, pursuant to this Section, the labeling of the dispensed product shall include the names of both medications together with the phrase ‘bioequivalent to’ or a similar language indicating that the prescribed medication was interchanged, except when the prescribing professional indicates otherwise in writing.

(6) …

(c) …

(d) …”

Section 2[sic].- This Act shall take effect immediately after its approval.
CERTIFICATION

I hereby certify to the Secretary of State that the following Act No. 85-2011 (S. B. 1711) of the 5th Session of the 16th Legislature of Puerto Rico:

AN ACT to amend Sections 5.02 and 5.03 of Act No. 247 of September 3, 2004, as amended, known as the “Puerto Rico Pharmacy Act,” in order to require that in the event that the pharmacist interchanges the prescribed medication for another one, in accordance with the legislation in effect, the labeling of the dispensed product shall include the names of both medications together with the phrase “bioequivalent to” or a similar language indicating that the prescribed medication was interchanged, except when the prescribing professional indicates otherwise in writing.

has been translated from Spanish to English and that the English version is correct.

In San Juan, Puerto Rico, on this 27th day of June, 2014.

Juan Luis Martínez Martínez
Acting Director