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January 2, 2017

LAW NO. 13,410, OF DECEMBER 28, 2016

Amends Law no. 11,903, of January 14, 2009, to dispose of the National System Of Medication Control.

THE PRESIDENT OF THE REPUBLIC
Let me know what the National Congress decrees and I sanction
The following Law:

Art. 1 The Law no. 11,903, of January 14, 2009, becomes with the following amendments:

"Art. 1. The National Drug Control System is created, To control the production, distribution, commercialization, dispensing and medical, dental and, if it contains medicinal products for human, veterinary, as well as the other types of movement provided by sanitary controls. " (NR)

"Art. 2. The competent federal health surveillance body shall determine, in its own rules, the categories of produced, distributed, marketed, dispensed or prescribed in the national territory subject to the National System of Medication Control.

Single paragraph. (***Revoked***). " (NR)

"Art. 3. The control shall be carried out by means of an individual identification of medicines with the use of capture, storage and electronic transmission technologies of data.

§ 1. Packages of all registered medicines will receive specific identification based on capture system, storage and electronic transmission of data, minimally containing the following information:

I - registration number of the medicinal product in the surveillance organ sanitary authority;
II - the unique serial number of the medicinal product;
III - batch or starting number of the medicinal product;
IV - date of validity of the medicinal product;
V - (***repealed***);
VI - (***repealed***);
VII - (***repealed***);
VIII - (***repealed***).

§ 2. The competent federal health surveillance body and the may include other information, in addition to those presented in items I, II, III and IV of § 1. " (NR)

"Art 4. The National Drug Control System should have a database centralized in an institution the federal government, for storage and consultation of the medicines under its responsibility.

§ 1. Each member of the chain of movement of medicines is responsible for transmitting to the database the all the records on the circulation of medicines in their custody.

§ 2. The information shall be consolidated in a bank of data that allows consultation by the health surveillance body competent authority when requested.

§ 3. Commits a sanitary infraction to the establishment that to communicate any information regarding the movement of medication.

§ 4. The member of the chain of movement of medicines will have access, for consultation, only to the data he inserted into the system and those strictly necessary for the addition new information on the movement of medicines in their custody.

§ 5. The information contained in the database provided for in the caput should be treated as confidential information, and may not be disclosed or marketed. "

"Art 5. The competent federal health surveillance body regulate the operational aspects of the National System of Control of Medicines within four months, extendable by justification.

I - (***repealed***);

II - (***repealed***);

III - (***repealed***).

Single paragraph. After the regulation of that deals with the caput, the other stages of implantation of the System National Drug Control Office shall obey the following deadlines:

I - up to one year, so that industry, importers and representatives of distribution and retailing chosen by the competent federal health surveillance authorities may, on an experimental, receive and transmit data concerning, at a minimum, three batches of medicinal products containing the information in items I, II, III and IV of § 1 of Art. 3;

II - up to eight months after the end of the stage established in the paragraph I of this paragraph so that the results obtained during the experimental phase are subject to analysis, correction and reporting of validation by the competent federal health surveillance body, through the Management Committee;

III - up to three years after the end of the stage established in the paragraph II of this paragraph, for the full implementation of the National System of Control of Medications. "(NR)

Art. 2 This Law shall enter into force on the date of its publication.

Single paragraph. The deadlines set forth in Art. 5 of the Law on 11,903, of January 14, 2009, shall become effective as of the date of publication of this Law.

Art. 3 The sole paragraph of Art. 4 of the Law on 11,903, dated January 14, 2009.

Brasília, December 28, 2016; Of Independence and 128th of the Republic.

MICHEL TEMER
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