

DECREE - 8,077, OF AUGUST 14TH, 2013

Regulates the *registro*, control, and monitoring of the products addressed by Law 6,360, of September 23rd, 1976, and the conditions for the operation of companies subject to sanitary licensing, within the scope of health surveillance, and makes other provisions.

The PRESIDENT OF THE REPUBLIC, in the exercise of the powers vested in her by Article 84, caput and subsections IV and VI, item "a", of the Brazilian Federal Constitution, and in view of the provisions of Law no. 6,360, of September 23rd, 1976, and of Law 9,782, of January 26th, 1999, hereby DECREES:

CHAPTER I
PRELIMINARY PROVISIONS

Article 1. This Decree hereby regulates the *registro*, control, and monitoring of the products addressed by Law 6,360, of September 23rd, 1976, and the conditions for the operation of companies subject to sanitary licensing, within the scope of health surveillance.

CHAPTER II
CONDITIONS FOR THE OPERATION OF COMPANIES

Article 2. The performance of the activities related to the products referred in Article 1, of Law no. 6,360, 1976, shall depend on the authorization of the Brazilian National Health Surveillance Agency (Anvisa) and on the licenses granted by the competent State, Federal District, or Municipal health organs, provided that the technical requirements set forth in regulations issued by such organs are complied.

Sole Paragraph. The activities conducted by the company and the respective categories of the products related to them shall be explicitly indicated in the authorization and licenses aforementioned in the caput.

Article 3. In order to be licensed by State, Federal District, or Municipal authorities, the establishments that perform the activities herein addressed in this Decree shall:

- I - have the authorization aforementioned in the caput of Article 2 issued by Anvisa;
- II - prove technical and operational capacity and availability of indispensable facilities, equipment, and apparatus in conditions required for their intended purpose;
- III - have means for quality assurance of the products and activities carried out by the establishment, according to specific regulations;
- IV - have trained human resources for the conduction of their activities; and
- V - have means capable of preventing, eliminating, and mitigating environmental risks posed by the activities performed by the establishment and that may have harmful effects on health.

Article 4. Establishments shall have independent sanitary licenses, even if located in the same Municipality or in Federal District and if they belong to only one company.

Article 5. The establishments that perform the activities herein addressed in this Decree are hereby obliged to have a legally licensed technical manager¹.

Article 6. Public organs and entities that conduct the activities addressed in Law 6,360, 1976, shall not depend on operating licenses, being, however, subject to the requirements related to adequate facilities, equipment, and apparatus and to technical assistance and liability.

CHAPTER III

REGISTRO OF PRODUCTS SUBJECT TO HEALTH SURVEILLANCE LEGISLATION

Article 7. The aforementioned products in Article 1 may only be object of the activities associated with them if registered at Anvisa and if they comply with their specific regulations.

Paragraph 1. The *registro* shall be issued within up to ninety days, counted from the submission date of the request, except in cases of failure to observe the provisions of Law no. 6,360, 1976, of the herein Decree, or of other pertinent standards.

Paragraph 2. In addition to the provisions of Article 41-A of Law no. 9,782, of January 26th, 1999, the analyses of the requests for *registro* of the following products shall have priority under the terms of Anvisa's specific regulation:

¹ Technical managers, in Brazil, must have a university degree and be associated to their respective professional council, which is responsible for regulating the working market of such profession and ensuring that every person working in this profession is legally licensed to do so and have their rights reinforced. This license is a relevant requirement due to the fact that technical managers are liable in court for everything related to the product/activities for which they are responsible [T. N.].

- I - strategic products for the Brazilian Unified Health System (SUS), as laid down in Act passed by the Minister of Health;
- II - products object of technology transfer to public organs and entities; and
- III - products with radical or incremental innovations manufactured in Brazil or that comply with their rule of origin or the Basic Manufacturing Process, provided that their technological core is also manufactured in the country.

Paragraph 3. Should there not be risks to the population's health or to the inspection of production and circulation activities, the *registro* of the products herein addressed in this Article may be object of Anvisa regulation in order to:

- I - simplify and speed up procedures; and
- II - establish priorities and goals of performance addressed in a clause of the management contract referred by Article 19 of Law no. 9,782, 1999.

Paragraph 4. Anvisa may exempt from *registro* insecticides, immunobiological products, medications, and other strategic supplies when acquired through international multilateral organisms and intended to be used in public health programs by the Ministry of Health and its related entities.

Paragraph 5. In cases of serious risks to health and if the unavailability in the domestic market of registered therapeutic substitutes has been proven, Anvisa may establish simplified procedures to enable the supply of medications by the SUS.

Article 8. The *registro* of the aforementioned products in Article 7, its alterations and revalidations are hereby subject to the compliance with the provisions of Law 6,360, 1976, of the herein Decree, and of other technical requirements laid down in Anvisa's specific regulations.

Paragraph 1. The *registro* herein addressed in Article 7 shall be valid for five years and may be revalidated for equal and successive periods of time, kept the initial *registro*.

Paragraph 2. The revalidation of a *registro* shall be requested with a maximum 12-month notice and a minimum of six months, counted from the expiration date of such.

Paragraph 3. Having complied with the provision of paragraph 2, the *registro* shall be automatically revalidated regardless of Anvisa's decision, should such decision have not been made until the expiration date of the *registro*.

Paragraph 4. Automatic revalidations shall be granted under the same terms and conditions the *registro* or its last revalidation has been.

Paragraph 5. Automatic revalidations shall not hinder the analysis of the request for revalidation, which may be confirmed or dismissed by Anvisa, according to the legislation in force.

Paragraph 6. The dismissal of the request for a *registro* revalidation that has been automatically revalidated shall lead to the cancellation of such.

Article 9. The products herein addressed in this Decree may not have names or designations that might lead to confusion with regard to their composition, intended use, indications, applications, instructions for use, and origin.

Sole Paragraph. The change in the name of a registered product before its commercialization is hereby allowed when requested by the company.

Article 10. The importation of products submitted to health surveillance legislation shall be subject to previous manifestation of Anvisa, which will set forth in specific regulations the technical requirements to be observed.

Paragraph 1. The procedures for the release of imported products intended for technological and scientific research shall be simplified according to Anvisa's specific regulation.

Paragraph 2. The importation by physical persons of the products herein addressed in this Decree, if not submitted to special control policies, in a quantity for individual use, and not intended for reselling or marketing, shall not depend on any authorization, as long as Anvisa's specific regulations are met.

Article 11. Products within the scope of health surveillance legislation, including those imported, shall only be available for use or consumption in their original packaging, unless otherwise provided in Anvisa's specific standards.

Sole Paragraph. The repackaging of imported bulk products in Brazil is hereby allowed, provided that the technical requirements laid down in Anvisa's specific regulation are met.

CHAPTER IV

CONTROL AND MONITORING ACTIVITIES OF PRODUCTS IN THE BRAZILIAN NATIONAL HEALTH SURVEILLANCE SYSTEM

Article 12. The following are in charge of the health surveillance activities addressed herein and in Law no. 6,360, 1976:

- I - Ministry of Health, with regard to the development, follow up, and evaluation of Brazilian national health surveillance policies and of the general guidelines from the Brazilian National Health Surveillance System;
- II - Anvisa, in the exercise of the powers vested by Law no. 9,782, 1999; and
- III - States, Federal District, and Municipalities, by the action of their competent health surveillance organs.

Article 13. Health surveillance officers, upon their control and monitoring activities, shall have the following powers and prerogatives, among others:

- I - free access to places where the aforementioned activities in Article 2, within any phase of processing, are subject to sanitary control, to documents, and to related data;
- II - conduction of patrol inspections and of inspections to investigate sanitary violations, drawing up the respective writs;
- III - collection of the necessary samples for fiscal or control analyses, drawing up the respective writs;
- IV - verification of the compliance with the health and hygiene conditions required for employees with regard to the aforementioned activities in Article 2;
- V - verification of the origin and sanitary conditions of the products;
- VI - partial or total interdiction of product batches and of the establishments where the aforementioned activities in Article 2 are performed due to the non-compliance with the applicable health surveillance legislation, drawing up the respective writs;
- VII - determination and inspection of the immediate uselessness of products whose alteration or deterioration is caught in the act, and arrest or interdiction of the rest of their batch; and
- VIII - filing and judgment of administrative proceedings, according to Law no. 6,437, of August 20th, 1977.

Article 14. Health surveillance actions shall have a permanent character and shall constitute a routine activity for health surveillance organs.

Sole Paragraph. When requested by the competent health surveillance organs, companies shall provide information or documents within the deadlines established in order not to hinder health surveillance actions and the measures that may be necessary.

Article 15. Health surveillance actions shall implicate in the inspection of every product herein addressed in this Decree, including those exempt from *registro*, as well as of manufacturers, distributors, storage and selling companies, and vehicles intended for product transportation, in order to ensure compliance with good practices and with the requirements made by the legislation in force.

Paragraph 1. Registration holders, manufacturers or importers, are responsible for ensuring and maintaining the quality, safety, and efficacy of their products until their final user in order to prevent risks and adverse effects on health.

Paragraph 2. The joint liability for maintaining the quality, safety, and efficacy of the products and for rational consumption encloses all other agents acting from production to consumption.

Paragraph 3. The advertising and publicity of products and brands by any communication means and their labeling are hereby subject to health surveillance actions and to Anvisa's specific regulations in order to prevent unethical commercialization practices and the transmission of inadequate or fraudulent information.

Article 16. Health surveillance actions shall include the detection, monitoring, and assessment of problems related to products and other technologies, as well as the inspection of studies conducted with new medications, especially during the phase of clinical studies carried out in human beings.

Sole Paragraph. Adverse events and technical complaints related to the products subject to health surveillance shall be notified to Anvisa for the purposes of monitoring, analysis, investigation, measures for communicating the population, and other actions to prevent, mitigate, or eliminate risks, according to the technical requirements laid down in Anvisa's specific regulations.

Article 17. Companies shall ensure the quality of the products subject to health surveillance policies by complying with the technical requirements laid down in Anvisa's specific regulations.

Article 18. The inspection of the organs part of the public administration or by entities established by such, which carry out the activities herein addressed in Article 2, shall observe the rules enforced for the control of other establishments subject to health surveillance, including those rules with regard to facilities, equipment, and technical assistance and liability.

CHAPTER V FINAL PROVISIONS

Article 19. The distribution of free samples of medications is hereby allowed if exclusive to doctors and dental surgeons, except samples of products that contain narcotic substances or that cause physical or psychic dependence.

Sole Paragraph. The number of pharmacotechnical units of samples shall correspond to the quantity regulated by Anvisa, and their labels shall contain the information "*USO SOB PRESCRIÇÃO*"

MÉDICA" ("USE UNDER MEDICAL PRESCRIPTION"), according to the labeling requirements laid down in specific regulations.

Article 20. Anvisa shall elaborate and publish the list of substances and medications subject to special control, addressed in Article 66 of Law no. 11,343, of August 23rd, 2006.

Article 21. At the request of the Brazilian National Commission of Technology Incorporation into the SUS (Conitec), Anvisa shall issue an authorization of use for the supply, by the SUS, of registered medications and products in cases their intended use differs from that approved in their *registro*, provided that the scientific evidence on the efficacy, accuracy, effectiveness, and safety of such medications and products has been demonstrated by Conitec for the intended use requested.

Article 22. Medicinal plants intended to be used as vegetable drugs are hereby exempt from *registro*, according to the criteria established in Anvisa's specific regulations.

Sole Paragraph. The effectiveness of vegetable drugs may be acknowledged based on their traditional use and on previous experiences in Brazil and overseas.

Article 23. The company's intention to temporarily or decisively interrupt the manufacture or importation of registered medications supplied to the domestic market shall be notified to Anvisa with a minimum six-month notice.

Sole Paragraph. The minimal deadline aforementioned in the caput may be extended for up to 12 months, according to Anvisa's regulation, which shall define the technical criteria for the cases of interruption to the manufacture or importation referred in this Article in order to prevent market shortage supply.

Article 24. Notwithstanding other legal penalties - including those criminal -, physical and legal persons, technical managers, and legal representatives shall be civilly and criminally liable, under the terms of Law no. 6,437, 1977, for sanitary violations that resulted from the failure to observe the provisions of Law no. 6,360, 1976, of the herein Decree, and of other health surveillance standards.

Article 25. The following are hereby revoked:

- I - Decree no. 79,094, of January 5th, 1977; and
- II - Decree no. 3,961, of October 10th, 2001.

Article 26. This Decree shall come into force on the date of its publication.

Brasília, August 14th, 2013; 192nd of Independence and 125th of Republic.

DILMA ROUSSEFF
Alexandre Rocha Santos Padilha