Decree , IN IN 2017

Regulates Law No 12.305 of 2 August 2010, and establishes the Reverse Logistics Medications Discarded by the Consumer.

THE PRESIDENT OF THE REPUBLIC , in the use of the attributions granted by art. 84, sections IV and VI, paragraph "a" of the Constitution, and in view of the provisions of Law No. 12.305, of 2 August 2010, and Decree No. 7404 of December 23, 2010, which regulates.

DECREES:

Art. 1 º Reverse logistics of medicines discarded by the consumer is instituted with the participation of importers, manufacturers, distributors, traders and consumers according to with the provisions of Law No. 12.305, of August 2, 2010, which established the National Policy Solid Waste and Decree No. 7404 of December 23, 2010.

Art. 2 For the purposes of this decree, the following definitions apply:

I - packaging: the act of packing, sealing, weighing and labeling bags or boxes which, for contain the discarded drugs in the container dispenser. Such bags or boxes shall, in addition to being sealed and weighed, contain a label with mass information expressed in kg of drugs contained therein and are resistant to rupture, puncture, leakage, and are capable of provide leaktightness of the waste;

II - primary storage at the point of receipt: temporary storage inside the drugstores and pharmacies, of the bags or boxes containing the drugs discarded by consumers in the container dispenser. In the case of the storage of discarded bags or boxes within the scope of collection campaigns, the primary storage should be carried out in a place determined by the state or municipal environment;

III - secondary storage at the point of consolidation: bag storage or containing the packaged, sealed, weighed and labeled medicinal products in a dispensers until the external collection stage is carried out;

IV - anti-return: mechanism to prevent access by unauthorized persons to drugs that have already been discarded by consumers in the container dispenser;

V - collection campaigns: collection of drugs discarded by the consumer, carried out in pharmacies, drugstores or other points located in municipalities with a population equal to or less than

30.000 inhabitants and that can have periodicity greater than the regular collection, realized in fixed points;

VI - traders: companies in the pharmaceutical trade sector represented by pharmacies and drugstores;

VII - consumer: natural person who, for the purposes of this regulation, discards medicines of human use overdue or in disuse, from home use;

VIII - external collection: collection of bags or boxes containing medicines discarded by the the secondary storage point at the point of consolidation to proceed transportation to the treatment site and environmentally appropriate final disposal of tailings;

IX - container dispenser: equipment for receiving and storing insurance for home use drugs that have expired or are not used, discarded by the consumer and which containing bags or boxes for the disposal of discarded medicinal products, which

can be removed without damaging the equipment. In addition to this feature the container dispenser shall be provided with a check-out device and display to provide visual checking for verification of its volumetric capacity;

X - distributors: members of the pharmaceutical industry responsible for transportation and distribution of medicines;

XI - Primary packaging: original packaging that is in direct contact with the medicines, such as blisters, tubes, jars, jars, etc .;

XII - secondary packaging: packaging designed to contain one or more packages such as blister packs, ointments, etc .;

XIII - manufacturers and importers: representatives of the production sector importing medicines;

XIV - reverse logistics of drugs discarded by the consumer: instrument of economic and social development characterized by a set of actions, procedures and means intended to enable the collection and reimbursement of drug residues to the business sector for environmentally appropriate final destination;

XV - fixed collection and storage points: points inside the drugstores and pharmacies where the container dispensers used for the medicines. These points must be located in places visible within the establishments commercial and contain all the instructions described in § 2 of art. 3 º ;

XVI - mobile points of collection and storage: points located in places defined in representatives of the pharmaceutical sector (trade, distributors and industry), after consultation and approval of the municipal or state environmental agency in which the installation will be carried out temporary dispenser (s), container (s) for the collection campaign defined in subsection V of this article;

XVII - primary storage point: a place intended for the temporary storage of (bags or boxes) containing the drugs discarded by the consumer in order to facilitate collection and transportation to the secondary storage points; and

XVIII - secondary storage point: place intended for the storage of containing medicinal products discarded in a place indicated by merchants, distributors of medicines to be stored until the collection and transport environmentally appropriate final disposal sites.

Art. 3 Consumers should dispose of overdue disused or unfit for consumption in drugstores and pharmacies indicated by merchants, distributors, manufacturers and importers, provided that they comply with the standards established by the National System of Environment - SISNAMA, of the National Health Surveillance System - SNVS and of the National System of Metrology, Standardization and Industrial Quality - SINMETRO and the of this decree.

§ 1. Information on pharmacies and drug stores in which consumers can the disposal of medicinal products shall be provided within the scope of the advertising campaign specified in Art. 11 of this decree.

§ 2 º Disposal of medicines by consumers should be made in accordance with instructions described in the disclosure material fixed in a visible place, inside drugstores, pharmacies or, in the case of the campaigns provided for in item V of art. 2 º at other collection points.

Art. 4 The drugstores and pharmacies are obliged to acquire, deploy and maintain, in interior of its establishments, container dispensers in order to less a fixed point of collection and storage of drugs discarded by consumers for every 30,000 inhabitants.

§ 1. The fixed points of collection and storage will be made available in accordance with the described in art. 2, item XV of this decree.

§ 2. The fixed points of collection and storage will receive at least one dispenser container to be used for the disposal of medicines, which should be fitted with a access to unauthorized persons.

§ 3 º The container dispenser shall contain the words: "Discard Medicines Overdue, Disused or Improper for Consumption "and should contain other graphic resources, as schematic figures, to help the consumer safely dispose of medicines.

Art. 5 º Drug stores and pharmacies are also obliged to provide a safe place to the primary storage point inside the store.

§ 1. The site will be mentioned in the heading for the temporary custody of containers medicinal products discarded by the consumer, in accordance with the definition contained in subsection XVII of art. 2 of this decree until such waste is transported to a storage point as described in item XVIII of art. 2 º .

§ 2 The drugstores and pharmacies should to register and report on defined system in art. 9 º , the mass of medicines in kilograms.

§ 3 Registration defined in § 2 must be made before shipment of the containers containing medicinal products discarded for transport from the primary storage point to the point of secondary storage.

containing the medicinal products discarded by the consumer, from the point of storage to the secondary storage point as described in item XVIII of art. 2 º .

Art. 6 Distributors of medicines are obliged to collect

Single paragraph. Distributors of medicinal products are required to register and system defined in art. 9, the mass in kilograms of drugs received at the point of secondary storage, before such waste is shipped for treatment and environmental disposal.

Art. 7 The pharmaceutical companies are obliged to make by himself or by contracts, provided that they are duly authorized by the bodies SNV, the transport of drugs discarded by secondary storage to final treatment sites and environmentally appropriate final disposal of tailings.

Single paragraph.

importers of drugs The transport of the part in the cost of each company in the Brazilian market and

Art. 8 Manufacturers and importers of medicinal products are obliged to pay for the disposal of waste generated in the reverse logistics of in accordance with the sanitary and environmental standards established by the organs of the National Environmental Health System - SISNAMA and the National Health Surveillance System - SNVS in its respective areas of activity.

Single paragraph. Manufacturers and importers of medicinal products should register and inform, in the system defined in art. 9, the mass in kilograms of drugs collected at the point secondary storage and forwarded for treatment and final destination environmentally proper.

Art. 9 Importers, manufacturers, distributors and traders of medicinal products shall, within 60 days of the publication of this decree, establish a computerized system for the provision of information, in the form of an annual report, referring to the volume of medicines collected, transported and forwarded for treatment and environmentally appropriate final destination.

Article 10 The computerized system shall generate the annual report containing at least the the following information to be made available annually to the Ministry of the Environment:

I - number of municipalities served by the reverse logistics logistics system;

II - number of fixed points collection and storage in each municipality served by the reverse logistics systems;

III - number of collection campaigns carried out and names of municipalities where carried out in accordance with the code of Brazilian municipalities of the Brazilian Institute of Geography and Statistics - IBGE;

IV - mass of medicines discarded by consumers in kilograms per point of fixed collection, per year;

V - mass of medicines discarded by consumers in kilograms, in collection campaigns, by municipality, per year;

VI - mass of medicines discarded by consumers in kilograms per state of the federation, both in fixed points and in collection campaigns, per year; and

VII - total mass of drugs discarded by consumers in Brazil, in kilograms per year.

Single paragraph. The deadline for the beginning of data availability generated by the referred to in art. 9 is 1 year after the establishment of , taking into account the time limit set in that article.

Article 11 With the purpose of publicizing the reverse logistics of drugs discarded by consumers, traders, distributors, manufacturers and importers of medicinal products should disclose the existence of collection at fixed points, informing its location, as well as the realization of the campaigns collection described in item V of Article 2, indicating, in this case, local, date and period in which will be carried out.

Single paragraph. The disclosure referred to in this article shall be carried out by means of ads on radios, newspapers, advertisements on television and on the Internet.

Article 12 Importers, manufacturers, distributors and the creation of a management entity that should contain at least the requirements described in the Annex to this Decree.

Art. 13 In compliance with the provisions of § 2 of art. 15 of Decree 7404 of 2010, this decree should be evaluated by the Steering Committee for the Implementation of Reverse Logistics Systems CORI, within five years of its entry into force, in order to review.

Art. 14 Non-compliance with the provisions of this decree, subjects violators to the legal penalties to which they are subject, in particular those provided for in Law No. 12,305, of 2010 establishing the National Policy on Solid Waste, the Law No. 6938 of 1981 establishing the Policy National Environment and Law No. 9605 of 1998, establishing the Environmental Crimes Law, and as in the respective regulations and other applicable standards.

Art. 15 This Decree shall enter into force on the date of its publication.

Brasília, de 2017; 196 Independence and 129 of the Republic.

ATTACHMENT

The management entity for the operationalization of the reverse logistics system for medicines discarded by the consumer is voluntary and must have at least the following structure and form of operation:

Companies in the pharmaceutical sector, including pharmacies, drugstores, distributors, importers and manufacturers of medicinal products are obliged to promote, through entity with its own legal personality and non-profit making the following actions:

Administer the deployment and operation of reverse logistics for discarded drugs by the consumer taking care that such waste is disposed of, collected, stored, transported, treated and disposed of properly disposed of in licensed landfills responsible public bodies;

To fulfill, in compliance with the responsibilities imposed by the applicable legislation, reverse logistics, conditions and deadlines that fit them under this decree;

Promote, if necessary to operationalize the reverse logistics system, the creation of more than one management entity, each company being allowed to join one or more entities, or otherwise demonstrate compliance with the provisions set forth in this decree;

Disclose between the members of the management entity and other holders of the responsibility reverse logistics of drugs discarded by the consumer which, according to the Policy National Solid Waste, participate directly in the drug market, the entire content of the involved in reverse logistics, especially as regards collection of discarded drugs in municipalities with less than 30,000 inhabitants, as defined in the attached decree;

Participate in the publicity campaigns and dissemination of the reverse logistics of medicines at fixed points as well as in the collection campaigns described in the attached decree;

Participate in the dissemination of reverse logistics of drugs discarded by consumer as described in article 11 of the decree;

Report to the Ministry of the Environment the information generated through the computerized form in the form of an annual report containing at least the information listed in Article 10 of decree.