

LAW
No 9323, date 25.11.2004
ON MEDICAMENTS AND THE PHARMACEUTICAL SERVICE

Article 1
SCOPE

This scope of this law is to establish the regulations related to the manufacturing, importing, exporting, trading, description, use, quality control and inspection of the activities related to the medicines used for people within the Republic of Albania.

Article 2
The area of application

This law applies to all the subjects, juristic and physical persons, state or private, local or foreigners that exercise activities foreseen by the dispositions of this law.

Not to be translated

CHAPTER XI

MEDICAMENTS INSPECTION

Article 54
Inspection of the activities.

1. The National Center of Drug Control is responsible for controlling every activity related to the pharmaceutical area.

This centre exercises its jurisdiction over:

- a. The activity of manufacturing, the environment, as well as the equipments used with the purpose of medicines manufacturing;
 - b. The wholesaling and the retailing as well as the storage conditions for the medicines;
 - c. The medicinal raw materials in addition to the auxiliary and packaging materials;
 - d. The medicines imported by the licensed subjects based on the dispositions of this law.
2. The National Center of Drug Control, in order to exercise its activity, collaborates with:
 - a. The structure of hygiene and epidemiology near the primary service office;
 - b. The Public Health Institute;
 - c. The authorities of the state police;
 - d. The authorities of the customs and the taxation offices;
 - e. The Institute of Veterinarian Researches;
 - f. The Inspectorate of Environment Protection.
 3. The inspection, controlling and collaboration methods are established with a Decision of the Council of Ministers.

Article 55

The inspection o the veterinarian medicines.

The National Center of Drug Control, in collaboration with the Laboratory of the National Veterinarian Inspection, shall inspect the medicaments to be used in those animals whose products (meat, milk, eggs, etc.) are to be used as human nutrition.

Article 56

The Surveillance and the Inspection.

1. The Ministry of Health, through the Pharmaceutical Directorate, exercises a regulatory inspection relating to the activity of the National Center of Drug Control, concerning the fulfilment of the tasks and the exercising of its responsibilities by the above-mentioned centre.
2. The regulations for exercising the inspection activity shall be established with a decision of the Council of Ministers.

CHAPTER XI

ADMINISTRATIVE VIOLATIONS

Article 57

Administrative violations

Not to be translated

Article 58

The suspension of the licensed activities and the removal of the license.

1. The pharmaceutical inspectors, when they ascertain an administrative violation, in accordance with the article 57, order the suspension of the activity until the examination of the matter from the Licenses Commission near the Ministry of Health, as well as the impediment or the confiscation of the respective medicines.
2. In its first meeting, the Licenses Commission decides the removal of the license for the subjects that have committed a violation referring to the article 57 of this law.

Article 59

The impediment, the confiscation, and the liquidation of the medicines.

The impeded or the confiscated medicines, which do not comply with the established standards, must be liquidated with a regular reporting, based on the methods established by the legislation concerning the environment protection. Its expensed must be provided by the violating subject. However, when the medicines are usable, they must pass to the administration of the Ministry of Health, accompanied by a regular documentation.