

# LAW OF THE REPUBLIC OF TAJIKISTAN

## ON INTRODUCTION OF AMENDMENTS AND ADDITIONS TO THE LAW OF THE REPUBLIC OF TAJIKISTAN "ON PHARMACEUTICALS AND PHARMACEUTICAL ACTIVITIES"

**Article 1.** To introduce following amendment and additions to the Law of the Republic of Tajikistan as of August 6, 2001 "On pharmaceuticals and pharmaceutical activity" (Bulletin of the Majlisi Oli of the Republic of Tajikistan, No. 7. Page 499 2001; 12 page 700 2003; 5 page 375 2007; No. 6, page 467 2008):

1. To add paragraphs 31, 32, 33 and 34 to the Article 3 that read as follows:

"Pharmaceutical substances are pharmaceuticals in the form of active biotechnological, biological, mineral or chemical substances that possess pharmacological features used for the production, manufacture of pharmaceuticals and determining their therapeutic efficacy.

Circulation of pharmaceuticals - development, preclinical and clinical researches appraisal, state registration, standardization and quality control, efficiency, safety, production, manufacture, storage, transportation, import and export to/from the territory of the Republic of Tajikistan and its dispensing, sale, use, application, advertisement and destruction of pharmaceuticals.

Invented name of the pharmaceutical is the name of a drug determined by its manufacturer.

Certificate of pharmaceutical product and medical supplies is a document that sets the legal status of a particular product as medical or pharmaceutical product and allows its use in healthcare.

2. Article 8:

- To add the words " pharmaceuticals and" in the title and after the "control" in the first part;
- To add second, third and fourth parts that read as follows:  
"State Control of pharmaceutical activity and pharmaceuticals in the Republic of Tajikistan is arranged over the production of drugs within the country and their import to the territory of the Republic of Tajikistan.

State control of circulation of pharmaceuticals includes the control over the clinical trials of drugs, quality, efficiency, production, manufacturing, storage, transportation, import/export to/from the territory of the Republic of Tajikistan, and dispensing, sale, use, application, advertisement and destruction of pharmaceuticals.

State control over the circulation of the pharmaceuticals is arranged via:

- Verification of compliance with the rules of laboratory and clinical practices in during the preclinical and clinical studies of drugs used in health and veterinary;

- inspections for compliance with the conditions and requirements of issued licenses;
- verifications of quality of drugs;
- studying and monitoring the effectiveness and safety of pharmaceuticals;
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8. Article 30:

- to add the words "and individual entrepreneurs" after the words "legal persons" in the first part;

- to add part 3 that reads as follows:

"Individuals with secondary or higher professional pharmaceutical education and who have a professional certificate in pharmaceutical activities may engage in pharmaceutical activities (intake, storage, retail sale of pharmaceuticals and medical goods) as individual entrepreneurs after the obtaining of a certificate of state registration as an individual entrepreneur";

- Third, fourth and fifth parts shall be considered as parts four, five and six respectively.

**Article 2.** Present Law shall come into force after its official publication.

**President  
Republic of Tajikistan**

**Emomali Rahmon**

Dushanbe  
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# 861

