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; rules for the organization of production, quality control of pharmaceuticals, wholesale trade of drugs, manufacturing and dispensing of drugs, storage and disposal of pharmaceuticals;

- 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;
- obtaining information on prices and margins (markups) from state agencies and entities handling the circulation of pharmaceuticals;
- second and third parts shall be considered as part 5 and 6 respectively.

3. To replace the word "institutions" with "legal persons and individual entrepreneurs" in the second part of the article 10.

4. To complement Part 2 of the Article 12 with the wording "as well as pharmaceutical substances" after the word "means."

5. To replace the words "in pharmacies" with the "legal persons and individual entrepreneurs that have a license for pharmaceutical activity" in the fourth part of the article 14.

6. To add the wording "legal persons and individual entrepreneurs" after the word "institutions" in the first part of the article 16.

7. Article 20:

- to replace the word "pharmacies" with the wording "pharmacies, including individual entrepreneurs" in the third part;

- to add fourth, fifth, sixth and seventh paragraphs that read as follows:

"State registration shall be prohibited, if:

- Two or more drugs having different compositions are produced under the same brand name;
- the same drug is manufactured by the same manufacturer under the different trade names and submitted for state registration as two or more drugs.

Registration certificate is given to the registered drug for the period of five years with indication of dosage forms and quantization (dosage).

Subsequent confirmation of the registration certificates is arranged prior to the expiration of the registration certificate by the Authorized agency of the Government of the Republic of Tajikistan responsible for the state control of pharmaceutical activities on the basis of the application of the holder of registration certificate.

Information on pharmaceuticals and medical products that have passed state registration at the demand of the natural or legal persons can be confidential if:

- a drug or its composition is not known to persons engaged in the similar activities and manufacturer has to keep it secret;
- secrecy is conditioned by its commercial value;
- Fourth and fifth parts shall be considered as parts eight and nine.

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 **Emomali Rahmon**
Republic of Tajikistan

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