Text of Russian Federation Decree and Resolution

"On carrying out controls on labeling pilot (identification) signs and monitoring over the circulation of certain types of drugs for medical use"

January 24, 2017

as translated by Google Translate on February 5, 2017

GOVERNMENT OF THE RUSSIAN FEDERATION

D E C R E E

on January 24, 2017 № 62

MOSCOW

On carrying out controls on labeling pilot (identification) signs and monitoring over the circulation of certain types of drugs for medical use

The Russian government **decides:**

1. Carry out on the territory of the Russian Federation in the framework of the priority project "Implementation of an automated system for monitoring the movement of drugs from the manufacturer to the end user to protect the public from counterfeit medicines and surgical removal from circulation of counterfeit and substandard drugs" labeling experiment with control (identification) marks and monitoring over the circulation of certain types of drugs for medical use (hereinafter - the pilot) in the period from February 1 to December 31, 2017

2. To approve the Regulations on the pilot on marking control (identification) marks and Monitoring the circulation of certain types of drugs for medical use.

3. To establish that:

Federal executive bodies authorized to oversee the pilot are, the Ministry of Health, the Ministry of Finance of The Russian Federation, the Russian Ministry of Industry and Trade, the Federal Service for the Supervision of Public Health and the Federal Tax Service;

The information system operator exercising information support of the pilot is The Federal Tax Service.

4. The Ministry of health Russian Federation Russian Federation Ministry of Finance, the Ministry of Industry and Trade of the Russian Federation, the Federal Service for the Supervision of Public Health and the Federal Tax Service until 1 February 2018 to assess the results of the pilot and submit a report to the Government of the Russian Federation.

5. Conducting the pilot carried out at the expense of budget allocations to The Ministry health The Russian Federation, the Ministry of Finance of the Russian Federation, Ministry of Industry and Trade, Federal Service for Supervision of Health and the Federal Tax authorities in the federal budget for the corresponding the financial year for administration and management in the sphere of established functions.

Chairman of the Russian Federation, D. Medvedev

APPROVED
Resolution of the Government
Russian Federation
on January 24, 2017 № 62

P O S I T I O N

To conduct a pilot on labeling control (identification) marks and monitoring over the circulation of certain types of drugs for medical use

1. This Regulation establishes a procedure for a pilot to control the marking (identification) signs of trafficking and monitoring of certain types of drugs preparations for medical use who are in civil trafficking in the Russian Federation (hereinafter - the pilot).
2. The objectives of the introduction of labeling of medicines control (identification) marks are:
    a) countering illicit drug production drugs on the territory of the Russian Federation;
    b) [protection] against the smuggling of drugs on territory of the Russian Federation;
    c) combating the illicit trafficking of drugs on the territory of the Russian Federation;
    d) combating unfair competition in the drug supply chain;
    e) standardization and unification of procedures and supply of accounting distribution of medicinal products, including purchased for public needs.
3. The objectives of the pilot are:
    a) determining the effectiveness and efficiency of the movement control system of drugs in the Russian Federation being elaborated from the manufacturer (importer) to final consumers in general, and each of the medicines market participants drugs individually to achieve the objectives referred to in paragraph 2 above;
    b) determining the changes to be made to normative legal acts of the Russian Federation governing the supply chain of medicines in the event of a decision to introduce monitoring of the movement of certain types of drugs;
    c) the definition of the technical capabilities of information systems in which the information provision will be piloted, and the need for its further development.
4. Identification of drugs with control (identification) marks for the purpose of the pilot is carried out by manufacturers of drugs with the use of a two-dimensional bar code.
   Application of this labeling does not require amendments to the registration dossier for the drug.

5. The pilot will be carried out on a voluntary basis on the basis of applications [submitted by] members of the pharmaceutical supply chain in the period from February 1 to December 31, 2017.
   Priority for participation in the pilot are drugs intended for people with hemophilia, cystic fibrosis, pituitary dwarfism, Gaucher disease, malignant neoplasms of lymphoid, hematopoietic and related tissue, multiple sclerosis, persons after transplantation of organs and (or) tissues.
6. To carry out the pilot, the Russian Federation Ministry of Health in coordination with the Ministry of Finance of the Russian Federation, the Russian Ministry of Industry and Trade, the Ministry of Communications and Mass Communications of the Russian Federation, the Federal Service for oversight of Public Health and the Federal Tax Service are approved by the guidelines, which are set including:
   a) encoding rules (code structure, formation method, format);
   b) the information system requirements;
   c) requirements for the equipment used to read the code;
   d) the procedure for transmitting and sharing information;
   e) the procedure for interaction between the information system with the existing information resources;
   f) the procedure for submitting applications for participation in the pilot and the accompanying documents, as well as the standard form of the application;
   g) the procedure for registration of participants in the system;
   h) the procedure for entering information into the system, including a list of the information provided;
   i) the procedures for monitoring and evaluation of pilot results;
   j) functions of participants in the pilot and how they interact, including the timing and basis for a decision on the withdrawal a drug from the market.
7. The participants of the pilot are:
   a) The Ministry of Health, Ministry of Industry and Trade of the Russian Federation, the Ministry of Finance of the Russian Federation Federal Tax Service, Federal Customs Service, Federal Service for oversight in the sphere of public health, the territorial bodies of the Federal Service on Surveillance in Healthcare;
   b) stakeholders in the pharma supply chain (drug manufacturers, wholesale drugs organization, persons performing foreign manufacturer, retailer organizations medicines, medical institutions) who have submitted applications to participate in the pilot.
8. Coordination of the implementation of this Regulation [will be] carried out [by] the design committee for the implementation of the priority project "Implementation of an automated system for monitoring the movement of drugs from the manufacturer to the end user to protect the public from

counterfeit medicines and surgical removal from circulation of counterfeit and substandard drugs," in accordance with the passport of this priority project and its master plan.

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