GOVERNMENT OF RUSSIAN FEDERATION

RESOLUTION
dated __ _____ 2016, #___

ABOUT AN EXPERIMENT ON MEDICAL PRODUCTS MARKING WITH CONTROL (IDENTIFICATION) SYMBOLS AND MONITORING OF DEFINED TYPES OF MEDICAL PRODUCTS

The Government of Russian Federation decrees:

1. To conduct an experiment on medical products marking with control (identification) symbols and monitoring of defined types of medical products (hereafter experiment) within the territory of Russian Federation, during the period of January 1, 2017 – December 31, 2017.
2. To approve the attached Regulation on conduction of the experiment on medical products marking with control (identification) symbols and monitoring of defined types of medical products.
3. To define the following:
    a. Federal organs of the executive power authorized for the provision of the conduction of the experiment, include Ministry of Health of Russian Federation, Ministry of Finance of Russian Federation, Ministry of Industry and Trading of Russian Federation, Federal Service for Surveillance in Healthcare, and Federal Tax Service.
    b. An operator of information system providing the informational support for the experiment, is Federal Tax Service.
4. Ministry of Health of Russian Federation, Ministry of Finance of Russian Federation, Ministry of Industry and Trading of Russian Federation, Federal Service for Surveillance in Healthcare, and Federal Tax Service should:
    a. Assess the results of the experiment before the February 1, 2018, and provide the Government of Russian Federation with a correspondent report.
5. The experiment will be conducted out of budget assignations established for Federal Tax Service.

Head of the Government
of Russian Federation
D. MEDVEDEV

Approved by the
Resolution of the Government
of Russian Federation
dated __ _____ 2016, # _____

REGULATION ON CONDUCTION OF THE EXPERIMENT ON MEDICAL PRODUCTS MARKING WITH CONTROL (IDENTIFICATION) SYMBOLS AND MONITORING OF DEFINED TYPES OF MEDICAL PRODUCTS

1. This Regulation establishes the order of the conduction of the experiment on medical products marking with control (identification) symbols and monitoring of defined types of medical products, which are in civilian circulation within the territory of Russian Federation (hereafter experiment).
2. The objectives of the implementation of a system of medical products marking with control (identification) symbols are:
    a. Counteraction to illegal production and/or import of medical products within the territory of Russian Federation.
    b. Counteraction to illegal circulation of medical products within the territory of Russian Federation.
    c. Counteraction to unethical competition in the area of medical products circulation.
    d. Standardization and unification of the procedures of the accountability of supplies and distribution of medical products, including purchased for state needs.
3. The objectives of the experiment are:
    a. To evaluate efficacy and efficiency of the developing system of control of the movement of medical products within the territory of Russian Federation, from manufacturers (importers) to final consumers, in general as well as separately for each market participant, for the objectives listed in the item 2 of this Regulation.
    b. To define necessary changes and additions for laws and regulations of Russian Federation which regulate the area of the medical products circulation, in case of a positive decision on the implementation of monitoring of defined types of medical products.
    c. To define technical possibilities and necessity of additional development of information system which will be used for the informational support of the experiment.
4. In this experiment, the medical products marking with control (identification) symbols will be performed by manufacturers using two-dimensional data matrix (DataMatrix).
   This experimental marking does not require changes of the medical product dossier.
5. The experiment will be conducted on voluntary basis, according to applications of the subjects of medical products circulation, during the period of January 1, 2017 – December 31, 2017.
   For this experiment, priority will be given to the medical products intended to be provided to patients with hemophilia, cystic fibrosis, pituitary dwarfism, Gaucher disease, malignancies of lymphoid, hematopoietic, or similar tissues, multiple sclerosis, as well as patients with organ and/or tissue transplants.

6. For this experiment, Ministry of Health of Russian Federation in cooperation with Ministry of Finance of Russian Federation, Ministry of Industry and Trading of Russian Federation, Federal Service for Surveillance in Healthcare, Federal Tax Service, and Federal Customs Service will define methodological guidelines on the following issues:
    - Rules of coding (code structure, how it is formed, code format).
    - Requirements for the information system.
    - Requirements for the equipment for code reading.
    - Practice of the information transfer and exchange.
    - Practice of interaction between the information system and existing sources of information.
    - Practice of application for the participation in the experiment, list of necessary documents, application form.
    - Practice of the participants registration in the system.
    - Practice of introduction of data into the system, including a list of provided data.
    - Practice of interaction of the participants of the experiment, including timelines and bases for the decision about the termination of a medical product circulation.
7. Ministry of Health of Russian Federation, Ministry of Industry and Trading of Russian Federation, Ministry of Finance of Russian Federation, and Federal Service for Surveillance in Healthcare will provide the conduction of the experiment, as well as its methodological guidance and interaction with the participants.
8. The participants of the experiment include:
    a. Ministry of Health of Russian Federation, Ministry of Industry and Trading of Russian Federation, Ministry of Finance of Russian Federation, Federal Tax Service, Federal Customs Service, Federal Service for Surveillance in Healthcare, regional/local representative organs of Federal Service for Surveillance in Healthcare.
    b. Subjects of medical products circulation (medical products manufacturers, wholesale organizations, representatives of foreign manufacturers, retail organizations, medical organizations) applied for the participation in the experiment.

MEMORANDUM

for the project of Resolution of the Government of Russian Federation

«About an experiment on medical products marking with control (identification) symbols and monitoring of defined types of medical products»

The project of Resolution of the Government of Russian Federation «About an experiment on medical products marking with control (identification) symbols and monitoring of defined types of medical products» (hereafter project) was developed in accordance with the item 5 of the list of assignments of President of Russian Federation, after a meeting with members of the Government of Russian Federation on February 4, 2015 (List of Assignments #Пр-285, about the development and gradual implementation of automatic system of monitoring of medical products circulation from a manufacturer to a final consumer, using marking and identification of packaging, with the objective of providing effective control of circulating medical products quality and of counteracting their falsification), and in accordance with the assignment of II Shuvalov, the First Deputy of the Head of the Government of Russian Federation dated July 5, 2016 (Assignment ИШ-П13-3959, about the development of a legal act regulating the conduction of an experiment on selected medical products marking with control (identification) symbols, on a voluntary basis, starting on January 1, 2017, in Russian Federation.

This project involves conduction of the experiment on medical products marking with control (identification) symbols and monitoring of defined types of medical products with the following objectives:

- To evaluate efficacy and efficiency of the developing system of control of the movement of medical products within the territory of Russian Federation, from manufacturers (importers) to final consumers, in general as well as separately for each market participant, for the objectives listed in the item 2 of this Regulation.
- To define necessary changes and additions for laws and regulations of Russian Federation which regulate the area of the medical products circulation, in case of a positive decision on the implementation of monitoring of defined types of medical products.
- To define technical possibilities and necessity of additional development of information system which will be used for the informational support of the experiment.

The approval of the Resolution of the Government of Russian Federation «About an experiment on medical products marking with control (identification) symbols and monitoring of defined types of medical products» will lead to an increase of consolidated budget of Russian Federation.

FINANCIAL FEASIBILITY STUDY

for the project of Resolution of the Government of Russian Federation «About an experiment on medical products marking with control (identification) symbols and monitoring of defined types of medical products»

To calculate costs of the conduction of the experiment on medical products marking with control (identification) symbols and monitoring of defined types of medical products (Federal State Information System of Monitoring of Circulation of Medical Products), analytical data were used. These are data of costs of the development of the system of marking with control (identification) symbols for the products of the following type: Articles of clothing related to apparel and other items made of animal fur. The system was developed by Federal Tax Service according to the assignments of II Shuvalov, the First Deputy of the Head of the Government of Russian Federation (minutes #ИШ-П13-63пр dated September 25, 2015, minutes #ИШ-П13-67пр dated October 5, 2015, and minutes #ИШ-П13-90пр dated December 1, 2015).

Using the abovementioned data, the following calculations were performed:

Calculations of the person per month costs

# / #	Items of cost	Rate, %	Value (RUR)
1	Nominal monthly paid salary for 1 IT sphere employee (payroll)	-	109 771
2	Payments to the Pension Fund of Russian Federation, insured and funded parts (from payroll)*	22.00%	24 150
3	Payments to Social Insurance Fund on traumatic accidents (from payroll)	0.20%	220
4	Payments to Social Insurance Fund on disability and maternity (from payroll)	2.90%	3 183
5	Payments to Federal Compulsory Medical Insurance Fund (from payroll)	5.10%	5 598
6	Additional charges (from payroll)	50.00%	54 886
7	Profit (prime cost – payroll + Payments to the Pension Fund of Russian Federation + Payments to Social Insurance Fund + Payments to Federal Compulsory Medical Insurance Fund + Additional charges)	10.00%	19 781
8	VAT	18.00%	39 166
Total cost of a person per month, RUR:			**256 755**

Thus, to provide the conduction of the experiment on medical products marking with control (identification) symbols and monitoring of defined types of medical products, the increase of budget assignations on the type of expenses 242 (Purchase of goods, works, services in the area of information and communication technologies) will be the following:

In 2016: RUR 256 760 * 334 hours/month (labor intensity)= RUR 85 750 340.

In 2017: RUR 256 760 * 736 hours/month (labor intensity)= RUR 189 000 000.

Total: RUR 274 750 340.

The approval of the Resolution of the Government of Russian Federation «About an experiment on medical products marking with control (identification) symbols and monitoring of defined types of medical products» will lead to an increase of consolidated budget of Russian Federation.