ATLANTIS PRESS

Advances in Economics, Business and Management Research, volume 105

1st International Scientific and Practical Conference on Digital Economy (ISCDE 2019)

Information system for monitoring the movement of drug products

Greibo S.V.
First Moscow State Medical I.M. Sechenov University of the Ministry of Healthcare of the Russian Federation
Moscow, Russia
pr_nick@mail.ru

Pronkin N.N.
First Moscow State Medical I.M. Sechenov University of the Ministry of Healthcare of the Russian Federation
Moscow, Russia
pr_nick@mail.ru

Filippova O.V.
First Moscow State Medical I.M. Sechenov University of the Ministry of Healthcare of the Russian Federation
Moscow, Russia
pr_nick@mail.ru

***Abstract* — The development of modern information technologies in medicine allowed to introduce an information system of motion monitoring, which makes it possible to track each package of drug products. In Russia alone, more than 7 billion packages of drug products are produced and imported from other countries, which must be taken into account in more than 350 thousand subjects of circulation in a large territory. The article formulates the main tasks of the monitoring system. The expected participants of interaction within this information system are defined, and also their quantitative structure is defined. The list of departmental information systems of key participants of the labeling process is given, the analysis of costs for the development, implementation and operation of the system is made. Possible methods of automatic identification of drug product packages are given and their main characteristics are determined.**

Keywords — Information system for monitoring the movement of drug products, methods of automatic identification of objects, QR code

I. INTRODUCTION

The quality of treatment and preventive care to the population is largely determined by the availability of drug products. The variety of tasks in the uninterrupted supply of medicines to the population and the complexity of their solution put this problem among the most difficult ones facing public health service. At the same time medicine provision is one of the elements guaranteeing the national security of Russia.

The priority of the state policy of the Russian Federation in the field of the circulation of medicines is quality assurance, effectiveness and safety. The improvement of the state control and licensing system in the field of the movement of drug products, which is carried out by strengthening control at all stages of circulation, organizing the production, storage, transportation, dispensing, destruction of drug products, etc. play a critical part in this [1].

Current requirements for the medicine provision system throughout the country imply the use of latest information, the receipt of which is possible as part of the operation of an automated information system for monitoring the movement of drug products. The movement monitoring information system (information system) is designed to organize continuous monitoring of the movement of drug products from the manufacturer to the final consumer using individual (group) coded labeling and identification of drug product packages ensuring effective quality control of the movement of drug products and fight against falsification [2]. Its introduction will allow solving the following tasks on a new level:

- • protecting the population from substandard and counterfeit drug products that can cause damage to health;
- • providing an unlimited circle of consumers with the opportunity to verify the legality of registered drug products in civil circulation;
- • ensuring supply transparency and developing fair competition in the pharmaceutical market.

If earlier the drug product package of one production batch was identical, then with the introduction of this system a control identification mark on each packaging not only allows distinguishing between each drug product package, but also monitoring it in the subjects of the movement of drug products in co-operation with the information system.

The main tasks the information system confronts are:

- • strengthening drug products safety of the population;
- • significantly reducing the threat to life and health of the population when counterfeit and substandard drug products enter the market;
- • creating a system for tracking drug products at all stages of promotion from the manufacturer to the final consumer, as well as the creation of on-line monitoring of individual segments of the pharmaceutical market (volume, sales, stocks, etc.) that create a coherent picture of the drug products supply of the population and allowing it to optimize planning processes;

- • transparent monitoring of the availability of drug inventory purchased at the expense of the federal budget of the Russian Federation by medical organizations and their movement;
- • providing informational support to executive authorities in their activities to counter the circulation of falsified, unregistered or substandard drug products;
- • consumer control over the distribution of counterfeit, unregistered, substandard drug products, which ensures active participation of the population in monitoring the movement of drug products;
- • increase in the effectiveness of federal state supervision in the field of drug product circulation.

The main participants in the interaction within the information system (subjects of circulation) are:

- • Ministry of Health of the Russian Federation;
- • Ministry of Finance of the Russian Federation;
- • Ministry of Industry and Trade of the Russian Federation;
- • Ministry of Communications and Mass Media of the Russian Federation;
- • Ministry of Economic Development of the Russian Federation;
- • Federal Service for Supervision in the Sphere of Health Care;
- • Federal Customs Service;
- • Federal Tax Service;
- • manufacturers of drug products;
- • organizations involved in the wholesale trade of medicines, including those importing the latter into the Russian Federation;
- • pharmacy organizations;
- • medical organizations;
- • organizations engaged in the destruction of drug products;
- • drug products consumers (patients).

Table 1 presents quantitative characteristics of the subjects of the movement of drug products.

TABLE I. QUANTITATIVE CHARACTERISTICS OF SUBJECTS OF CIRCULATION OF MEDICINES IN THE RUSSIAN FEDERATION

Name of the subject of treatment	**Number**	**Source of information**
Russian manufacturers of drug products	410	[3]
Foreign manufacturers of drug products	500	[3]
The organizations of wholesale trade in drug products, including carrying out their import to the Russian Federation	2 321	[3]
Pharmacy organizations	117,600	[3]
Hospital organizations	5 300	[4]
Outpatient organizations	20 200	[4]
Organizations engaged in the destruction of drug products	2 094	[5]

The information system is integrated with such departmental information systems of key participants in the labeling process [6,7] as:

- • a unified register of drug product manufacturing authorization;
- • a unified register of licenses, including licenses issued by state authorities of the constituent entities of the Russian Federation in accordance with the transferred authority to license certain types of health care activities;
- • a unified state information system in the field of healthcare;
- • a unified state register of legal entities;
- • a unified state register of individual entrepreneurs;
- • state register of accredited branches, representative offices of foreign legal entities;
- • automated information system of the Federal Service for Supervision in the Sphere of Health Care;
- • a single automated information system of customs authorities;
- • information systems of drug products circulation entities.

According to the estimations of the Presidential Council for Strategic Development and Priority Projects [9], the information system for monitoring the movement of drug products from the manufacturer to the final consumer [9] includes more than 350 thousand participants in the system — subjects of drug products circulation, and it is planned to track more than 7 billion packages of drug products per year.

Table 2 presents total cost of the organizational, technical, methodological, informational and other measures necessary to achieve the stated goals of regulation.

The following methods were considered for automatic identification of packages of drug products in the information system:

- • a method for automatic identification of objects, in which data stored in so-called transponders or RFID tags are read or written by means of radio signals;

- • a bar code (a sequence of black and white stripes) applied to the packaging of the drug product, allowing reading by technical means;
- • a matrix bar code, which differs from a conventional bar code by reading technology and a large amount of information per print area unit.

Table 3 presents main characteristics of these methods for automatic identification of objects.

Table 3 shows that RFID tags by any definition compare favorably with other identification methods. However, the widespread use of glass, foil and other materials capable of shielding a radio signal in the manufacture of pharmaceutical packaging makes it impossible to fully utilize all the advantages of radio frequency technology. Bar coding does not allow a sufficient amount of information about the identification object to be placed in the control and identification mark, therefore, a two-dimensional QR code is used in the information system for monitoring the movement of drug products from the manufacturer to the consumer. It is applied to the packaging of the drug products using the ECC-200 error correction method [10] and applied with a quality class level of at least C [11].

TABLE II. THE TOTAL AMOUNT OF EXPENSES FOR ORGANIZATIONAL, TECHNICAL, METHODOLOGICAL, INFORMATION AND OTHER MEASURES NECESSARY TO ACHIEVE THE STATED OBJECTIVES OF REGULATION

Activities required to achieve objectives of regulation	**Description of the expected result**	**Amount of financing (RUB)**	**Source of financing**
Development of acts of the Government of the Russian Federation	The System operation procedure is regulated	0	Federal budget
The development of information systems (commissioning)	The commissioning	846 691 750	Federal budget
Ensuring the functioning of the system	The System operates in normal mode	273 438 350	Federal budget
Equipping workplaces at the level of state and municipal participants of the subjects of the Russian Federation	Workplaces are connected to the system	1 574 936 000	Budget of subjects of the Russian Federation
Service of state and municipal participants of subjects of the Russian Federation	Interaction with the system occurs in the normal mode	567 497 600	Budget of subjects of the Russian Federation
The connection of the commercial participants of the interaction and modernization of production	All participants are connected. Production modernized.	7 400 835 180	Private investment
Service of commercial participants of interaction	Interaction with the system occurs in the normal mode	228 566 320	Private investment

Source: consolidated report on the regulatory impact assessment of the draft regulatory act [3].

The information contained in the drug product packaging identification tool has the following structure (Fig. 1):

- • DataMatrix Symbol - a symbol with code 232 in the ASCII character table;
- • the first data group is the global identification number of the trade unit, consisting of 14 digital symbols, which is preceded by the application identifier (01);
- • the second data group is the individual serial number of the trading unit, consisting of 13 characters of a digital or alphanumeric order (Latin alphabet), which is preceded by the application identifier (21). The terminating character for this data group is a special delimiting character with code 29 in the ASCII character table;
- • the third group of data is the verification key provided to the issuers of identification means by the operator of the monitoring system as part of the verification code in accordance with this Regulation [9], consisting of 4 characters (numbers, lowercase and capital letters of the Latin alphabet), preceded by the application identifier (91). The terminating character for this data group is a special delimiting character with code 29 in the ASCII character table;
- • the fourth group of data is an electronic signature provided to issuers of identification by the operator of the monitoring system as part of the verification code in accordance with this Regulation [9], consisting of 88 characters (numbers, lowercase and uppercase letters of the Latin alphabet, as well as special characters), which is preceded by the application identifier (92).

TABLE III. THE MAIN CHARACTERISTICS OF METHODS FOR AUTOMATIC IDENTIFICATION OF OBJECTS

Characteristics	**RFID tag**	**A matrix bar code**	**Bar code**
Appearance			
Practical reading speed (midrange / sec)	> 500	5 – 10	5 – 10
The need for line of sight	Not important	Important	Important
The orientation of the object when reading	Not important	Important	Important
The possibility of simultaneous reading	Possible	Impossible	Impossible
Resistance to mechanical stress	Sustainable	Unstable	Unstable
The possibility of code forgery	Impossible	Possible	Possible

In addition, at the discretion of the issuer of identification tools, the following groups are allowed in the two-dimensional bar code up to the third and fourth data groups:

- • the fifth data group - the batch number of the drug product, consisting of no more than 20 characters of a digital or alphanumeric order (Latin alphabet), which is preceded by the application identifier (10). The terminating character for this data group is a delimiting character with code 29 in the ASCII character table;
- • the sixth data group - expiration date preceded by an application identifier (17). The record of numerical characters for the expiration date of a medicinal product consists of 6 characters in the format "year - month - day" ("YYMMDD").

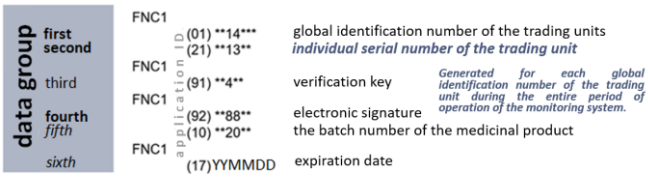

Fig. 1. Fig. 1. The structure information of the identification means

In those instances where the exact value of the expiration date in days ("DD") is not established on the production date, the issuer of identification means indicates the date value on the first or last day of the month in accordance with the expiration date approved by the regulatory documentation for the medicinal product.

Along with the two-dimensional code in the information system a group code is used, which is generated and applied to the transport (tertiary) packaging of the medicinal product by printing or labeling methods.

The group code is generated on the basis of the interstate standard [11], which is approved by the order of the Federal Agency for Technical Regulation and Metrology, and contains the following data structure:

- • application identifier;
- • group code extension character;
- • registration number of the subject of movement of drug products obtained in the information resource that provides for the accounting and storage of reliable data on goods for the relevant commodity nomenclature;
- • individual serial number of a trade unit;
- • checksum (a number calculated using a special algorithm from the previous digits and used to guarantee data integrity).

The information in the group code may be duplicated in the form of readable printed text.

II. Conclusion

Creating an information system should lead to the following results:

- • significant reduction of threats to life and health of the population of the Russian Federation that may be caused by falsified, counterfeit and substandard drug products;
- • a new mechanism for monitoring the targeted movement of drug products, followed by operational regulation of the availability of drug products in medical organizations;
- • continuous operational control of the market and its individual segments (volume, sales, stocks, etc.), on the basis of which it is possible to increase the effectiveness of drug products provision planning;
- • the possibility of developing mechanisms for prompt recall of drug products from circulation throughout the Russian Federation;
- • increase in the effectiveness of federal state supervision in the field of drug product circulation.

The introduction of the system will make it possible to achieve an economic effect in the form of improved planning in the provision of drug products, the possibility of a detailed market assessment and effective stock management throughout the country. Adequate provision of the population with drug products of good quality will improve the effectiveness of treatment, safety when using drug products in medical organizations and in the process of outpatient treatment. Specifying the targeted delivery of drug products for preferential categories is not only of medical importance, but also reduces social stress. Control over the movement of drug products and accurate inventory records will allow quick response in case of epidemiological situations.

The introduction of such a system is primarily a transparent market for the pharmaceutical industry, the ability to quickly see the costs of promoting their finished products. Disappearance of counterfeit products from the market will play a positive role for manufacturers.

The marking system allows providing access to an unlimited circle of persons to the database. The consumer can personally verify the legality of finding drug products in circulation, so everyone will feel the advantage of introducing this system.

References

[1] Prikaz Minzdrava Rossii ot 13.02.2013 N 66 (red. ot 07.04.2016) \"Ob utverzhdenii Strategii lekarstvennogo obespecheniya naseleniya Rossijskoj Federacii na period do 2025 goda i plana ee realizacii\".

[2] Prikaz Minzdrava Rossii ot 30 noyabrya 2015 g. N 866 «Ob utverzhdenii koncepcii sozdaniya federal'noj gosudarstvennoj informacionnoj sistemy monitoringa dvizheniya lekarstvennyh preparatov ot proizvoditelya do konechnogo potrebitelya s ispol'zovaniem markirovki»

[3] Svodnyj otchet o provedenii ocenki reguliruyushchego vozdejstviya proekta normativnogo pravovogo akta (dorabotannyj po itogam obsuzhdenij).Oficial'nyj sajt dlya razmeshcheniya informacii o

podgotovke federal'nymi organami ispolnitel'noj vlasti proektov normativnyh pravovyh aktov i rezul'tatah ih obshchestvennogo obsuzhdeniya, http://regulation.gov.ru/p/37232 (data obrashcheniya: 24.06.2019).

[4] Rossijskij statisticheskij ezhegodnik 2018 Federal'naya sluzhba gosudarstvennoj statistiki (Rosstat). S. 204.

[5] Reestr licenzij na deyatel'nost' po sboru, transportirovaniyu, obrabotke, utilizacii, obezvrezhivaniyu, razmeshcheniyu othodov I-IV klassov opasnosti. Oficial'nyj sajt Federal'noj sluzhby po nadzoru v sfere prirodopol'zovaniya. http://rpn.gov.ru/opendata/7703381225-rpnlicenses (reference date: 24.06.2019).

[6] Edinyj gosudarstvennyj reestr yuridicheskih lic.https://nalog-ru.com/egrul/

[7] Gosudarstvennyj reestr lekarstvennyh sredstv https://grls.rosminzdrav.ru/grls.aspx

[8] Edinaya sistema mezhvedomstvennogo elektronnogo vzaimodejstviya (SMEV). https://www.eos.ru/eos_products/solution/gosudarstvennyy_sektor/smev/

[9] Pasport prioritetnogo proekta \"Vnedrenie avtomatizirovannoj sistemy monitoringa dvizheniya lekarstvennyh preparatov ot proizvoditelya do konechnogo potrebitelya dlya zashchity naseleniya ot fal'sificirovannyh lekarstvennyh preparatov i operativnogo vyvedeniya iz oborota kontrafaktnyh i nedobrokachestvennyh preparatov\" (utv. prezidiumom Soveta pri Prezidente RF po strategicheskomu razvitiyu i prioritetnym proektam, protokol ot 25.10.2016 N 9)

[10] ISO/IEC 16022:2006 «Information technology -- Automatic identification and data capture techniques -- Data Matrix bar code symbology specification»

[11] ISO/IEC 15415:2011 \"Information technology - Automatic identification and data capture techniques - Bar code print quality test specification - Two-dimensional symbols\"

[12] ISO/IEC 15417:2007 "Information technology - Automatic identification and data capture techniques - Code 128 bar code symbology specification"