

## THE PHARMA INNOVATION - JOURNAL

### State administration of medicinal products turnover

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State control of pharmaceutical sector is suggested by automation of administrative processes of medical provision. This process is based on information technologies administration. Automation of medical organizations and public provision, creation of unified monitoring system of medicinal products turnover are studied. Incorporation of existing databases and those that are developing as a part of one integrated system of databases on the basis of unified national and branch classifiers is suggested.

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*Keyword:* State Administration, Administrative system of Medicinal Turnover, Automation, Monitoring, State Supervision, Unified National Classifier.

#### 1. Introduction

Provision of medical care is impossible without the use of medications (medicinal products- MP). Accordingly, the regulation of the pharmaceutical market is a complex and dynamic process directly involved in the delivery of quality health care.

Moreover, patients nowadays materially are interested to know how many and which MP they consume. Also, the media play an increasingly important role in shaping the demands of consumers, providing them with information about health and health care, and, of course, complex and diverse objectives of public administration, their roles in regulating <sup>[4]</sup>.

The paper discusses methods of state regulation of the pharmaceutical sector by automating management processes of drug provision, monitor of drug trafficking in the country, collection and processing of electronic information from all regions and providing healthcare payers and interested organizations with information accumulated in accordance with applicable law, and also timely informing of the responsible departments of the Ministry of Health (MOH) of Ukraine.

Purpose of the study is to establish the concept of management information system of medicinal maintenance (SMM).

#### 2. Results and discussion

Information obtained from the pharmaceutical activities supervisory and safety monitor, efficacy and quality of MP is the basis for objective analyze of the situation in the sphere of medicinal products, consisting in areas of professional evaluation and decision corresponding to the control and supervision, realizable and regulatory functions of the State service of Ukraine on Medicinal Products (Medicinal Products State service of Ukraine) of Ministry of Health of Ukraine.

Medicinal Products State service of Ukraine – is an executive authority in the field of health care quality and safety of MP, medical equipment and medical supplies that are in circulation and / or used in the health sector, approved for implementation in pharmacies and structural units, and licensing activities for the production of medicines, wholesale and retail sale of medicines. Responsible for submission is central

body (Medicinal Products State service of Ukraine) and territorial authorities (Medicinal Products State Inspection).

Medical software of management Information System should provide: automation maintaining to register medicines, medical supplies and medical equipment approved for the use in Ukraine, personalized accounting designation medicines to patients in the course of medical care, personalized accounting dispensing of medicines in pharmacies, accounting procurement and rational use of medicines, medical equipment and medical devices at all levels of care. In addition, should be the automation of accounting information on side effects of MP, monitoring of prices of medicines and medical supplies, monitoring of imports / exports of medicines and medical devices.

The basic indicators of concept offered:

- To eliminate duplicate data of entry and improvement of its reliability by identifying previously entered information;
- Opportunity to exchange messages between territorially distributed components;
- Improving of state regulation of MP – by providing automated information exchange between territorial authorities of Ministry of Health of Ukraine;
- The interaction with information systems of other departments and agencies in the framework of e-government.

Creation of SMM will ensure effective monitoring and operational decision- making based on analysis of collected information, will allow fully carrying out an oversight functions / for pharmacological activity of medical institutions.

For healthcare organizations engaged in pharmaceutical activities, the system will establish defective accounting organization, provide an opportunity to obtain timely and in information use of the latest achievements in the field of pharmacy.

For the population a single information databank of SMM will provide quantitative and qualitative information on medicines.

Based on SMM the following tasks are also possible:

- 1) To ensure continuous and convenient access to distributed information system resources to facilitate rapid decision-making;
- 2) Registration, accounting and operational information updates on all the building blocks;
- 3) Ensuring responsiveness of obtainaining of all required information in the form of reports, memos, etc. for decision on various aspects of the bases that are in any departmental level: republican, regional, territorial,
- 4) Providing access to the general public, information intended for dissemination.

Obviously, in order to realize the main objectives and carry out its functions the Medicinal Products State service of Ukraine within its jurisdiction has the right in accordance with legislation to make proposals on the development of concepts, strategies, development plans, public programs, normative legal acts in the field of MP, by definition list basic (essential) medicines and the suspension of the license for pharmaceutical activity. It is necessary to ensure the independence of the specific server objects used by the database server. Recent allow for different levels of the system to choose the optimal cost and performance environment for storing and processing data.

The structure of the Medicinal Products State Register information includes information about: trade, international non-proprietary name and synonym drug , its manufacturer , chemical name and composition, pharmacological properties of pharmacotherapy group, indications, contraindications, precautions, interactions with other MP and side effects , form release, dosage and Administration, conditions and terms of saving, and conditions of dispensing, date and number of the order of Ministry of Health of the

registration and other information necessary for subjects of pharmaceutical market [3].

Monitoring of prices of medicines by conducting system of prices, including international , CIP (foreign missions), wholesale (wholesalers), retailers ( pharmaceutical company).

Sample of pricing information on MP is carried out by:

- List of basic ( essential ) MP;
- medical supplies and medical equipment;
- manufacturing ;
- regions;
- Minimum, maximum and median (average) rates.

It should be noted that the information systems that operate in the field of MP, actively exploited at the level of "area - the republic". Due to the problem of financing the further improvement of information systems are not well developed. It is important to modify existing programs as well as development and implementation of new software products using modern computer technology.

Existing software tools in the field of MP are not focused on the introduction and storage of primary data at the level of district / city. Collection of summary is conducted at the regional and national level. It does not automate the process of sending accounting information to a superior level. Data transmitted and regulatory background are out of sync. Not include simultaneous updating of software used.

A significant amount of data accumulated in the operation of computer software in the field of MP cannot be used fully by all parties to the information exchange. Hospitals, health care organizations, pharmacies, which are the direct users of analytical and statistical data cannot obtain the necessary information on the rules using "on-line".

It is supposed to promote and extremely important in dealing with the task of tracing parallel imports. According to the European Federation of Pharmaceutical companies and associations (European Federation of Pharmaceutical Industries and Associations -

EFPIA), a significant proportion of the European pharmaceutical market is occupied by a company known as " parallel importers " parallel imports is about 15% of the pharmaceutical market of the UK , 11% - of Denmark , 9.3 % - Sweden , 8.9 % - 4.7% and the Netherlands - Germany.

According to IMS Health, by the end of II quarter 2002 parallel imports amounted to about 19% of the UK market for MP brands, but for the most valuable medicinal products reached 30 % and a total of 700 million pounds. In Sweden, a ban on "parallel imports" was canceled in 1995, p., Stimulating the influx of imports, which is currently more than 6 % MP market. Thanks to parallel imports partially satisfied the demand for MP is not due to the direct supply of pharmaceutical companies at higher prices, and by acquiring the same drug in another country where the manufacturing company has its marketing at a lower price. It provides cheaper MP and therefore expands access to the population.

Operation of the system should be based on the technology with the business processes, the implementation of which will unite into a whole system of participants, the flow of work roles and the perpetrators of these functions, and how to manage their sequence. SMM is built scalable, that supports an unlimited number of users as well as structural units. The system is a set of interconnected modules, each of which has its own functionality.

The implementation of the proposed concept should ensure effective implementation of the objectives of the regulation and control in the area of MP and through the application of modern computer and information technology, as well as effective monitoring and operational decision- making based on analysis of collected data, the implementation of full control and supervision functions for pharmaceutical activities of pharmacy and medical organizations. As already noted, the information exchange between system components must be implemented using server component objects in a single information health system.

Server performance of object provides several functions. The first function -is providing a

unified API for client applications by manipulating the properties of objects in the process of entering and editing data on the server database as a set of related normalized tables. It is necessary to ensure the independence of the specific server objects used by the database server. This will allow for different levels of the system to choose the optimal cost and performance environment for storing and processing data.

The first function of the server objects also provides a common technology base for building client applications to data entry health system. The server stores the configuration of objects, relations between them, the rules of manipulating objects. The objects in the system are patients, health care organizations, organizational units of Medicinal Products State service of Ukraine and continue in accordance with the object and dynamic business models.

Server objects must be able to flexibly build and modify the structure of objects at all levels of the hierarchy and automatic replication of changes to the required level and the appropriate settings. In addition, the server provides a unique system of objects (internal) identification for all levels of the hierarchy to those objects for which it is needed, and replication information for all items on all levels of the hierarchy.

The second feature - a distributed object replication configuration, the configuration database (groups of tables to store information about objects in the system) and the same data between the nodes of the system, combined in a hierarchical network. Replication functions must be performed server objects without having a permanent connection between servers of different nodes by sharing files via email or on physical electronic media.

Note that the server object will perform some basic functions and will implement in conjunction with application servers and database servers distributed collection and storage of medical information system (MIS).

Experience over recent years, experience has shown that the interaction of different systems is not possible in the absence of a single standard messages that integrates different systems into a

single distributed network data. And to ensure smooth operation of distributed objects need permanent, stable relationship between them that supports messaging servers .

SMM Information interaction with other information systems that operate within the MIS must be implemented by electronic messaging communication channels in accordance with the protocols on the " server objects" , and in accordance with the regulations specified contracts and agreements between the government customer organizations and developers of related systems. It is clear that such interaction of SMM ensured by adherence to common organizational, methodological and software engineering principles primarily through the unification of the indicators that are included in the statement of objects into account, on the basis of uniform classifications and directories, and application for information exchange related information systems unified telecommunication network protocols, forms and formats of data transmitted in electronic form.

External information systems act as information subsystems: medical and statistical, monitoring the epidemiological situation, the management of resources and so on.

### 3. Conclusions

Creation and implementation of medical information management system software is one of the most important elements of state regulation of pharmaceutical health sector.

The system should provide the following features for automating the Ministry of Health of Ukraine as keeping a register of medicinal products, medical devices and medical equipment approved for use in Ukraine, state forms, instructions, etc. interaction with other organizations working in the field of health care and abroad, accounting procurement and rational use of medicines, medical equipment and medical devices at all levels of medical care, monitoring of prices and so on.

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