

ОРГАНІЗАЦІЯ ТА ЕКОНОМІКА ФАРМАЦІЇ

Recommended by Doctor of Pharmacy, professor A.S.Nemchenko

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ANALYSIS OF THE NORMATIVE LEGAL REGULATION OF ACCOUNTABILITY OF MEDICINES AND MEDICAL PRODUCTS IN HEALTHCARE INSTITUTIONS

T.F.Muzyka, M.V.Zarichkova, M.V.Chesheva

National University of Pharmacy

Key words: pharmaceutical supply; medical and preventive institutions; medicines; medical products; distribution; accountability

The article studies the normative legal regulation of distribution and accountability of medicines and medical products (MP) in healthcare institutions and its features that are typical for medical and preventive institutions (MPI). It has been found what groups of medicines should be subjected to the strict record keeping and storage in MPI, and the list of accounting operations for medicines and MP (receiving, storage, dispensing (transfer), disposal) has been determined. The accounting process of medicines and MP from receiving in MPI to delivery to the patient has been analyzed. The need of its division into several components, namely inventory control of medicines and MP; accountability of medicines and MP in the hospital departments; accountability of medicines and MP at the post (in procedure rooms); accounting of medicines and MP, has been identified. It has been determined that each component performs a special task to meet the storage conditions, expiration date, control over the use and reporting. It has been found that in addition to the analytical accounting in MPI the book-keeping adapted for the budget organization activities within the current legislation is also carried out. The analysis has shown that the current legal regulation of medicines and MP under the conditions of MPI generally covers the whole range of measures for their distribution. It has been determined that the failure to carry out certain measures makes it impossible to control the entire way of medicines and MP from the moment MPI receive them till the patient uses them.

Currently, the pharmaceutical supply (PS) of patients treated in the conditions of the in-patient department in the medical and preventive institutions (MPI) with medicines and medical products (MP) is carried out using a wide range of drugs of domestic and import production. The issue of accountability and use of medicines and MP in MPI is always attracted attention of practitioners and researcher primarily because they are purchased with the budget money, thus requiring strict control over their use. The important thing is the organizational side of PS, the management of its distribution, and it has become the aim of this study.

Materials and Methods

During the study the methods of logical, historical, analytical analyses and sociological research were used. The normative legal regulation of distribution and accountability of medicines and MP in MPI was analyzed, and its features typical for healthcare institutions were determined.

Results and Discussion

It has been determined that the regulatory framework dealing with these issues began forming in 1991 and got the current state only in 2005 with the publication of a number of laws by the Ministry of Health (MOH) of Ukraine. The main of them is the law of the Ministry of Health of Ukraine dated 19.07.2005 №360 "On approval

of prescribing and order requirements for medicines and medical products. Dispensing of medicines and medical products in pharmacies and their subdivisions. Instruction regarding storage, recording and disposal of prescription forms and order requirements". This law regulated the strict record keeping and storage of individual groups of drugs [4].

Another important point was control of narcotic drugs, psychotropic substances and precursors regulated by a separate law of the Ministry of Health of Ukraine dated 21.01.2010 №11 "On approval of procedures for distribution of narcotic drugs, psychotropic substances and precursors in healthcare institutions of Ukraine" [7].

The whole complex of accounting operations within MPI includes receiving, storage, dispensing (transfer), and disposal. Receiving medicines and MP by MPI and their incoming control is fully regulated by the current legislation and is transparent and open for its implementation and monitoring. The way of medicines and MP within MPI from their receiving to delivery to the patient is the most time-consuming and difficult because of the necessity of taking into account each name and dosage form of drugs.

Until recently, this part of the regulation of medicines and MP was difficult to perform and control both by

a person in charge and regulatory authorities due to the guidelines on these issues that were too outdated. Therefore, the local healthcare authorities created the departmental instructions in various regions of the state. Firstly, the instructions were recommended, and secondly, the individual requirements were set in each region leading to a variety of accountability. The organizational and analytical components of accountability, the document management in MPI were streamlined together with the publication of the law of Ministry of Health of Ukraine dated 09.09.2014 №635 "On approving the Guidelines for accountability of medicines and medical products in medical and preventive institutions" [1, 6].

To implement the European standards for MPI the opportunity is given for each healthcare institution to introduce the position for a pharmacy specialist by adjusting the staff schedule. Thus, most MPI have such professionals as the part of their staff, and it certainly provides a qualitative incoming control and clear bringing drugs, MP and other goods on charge for the uninterrupted treatment process. Further persons in charge take part in the accounting process of these products, they are usually nurses appointed by medical administration.

The whole accounting process of medicines and MP from receiving in MPI to delivery to the patient was conditionally divided into several components, namely:

1. Inventory control of medicines and MP.
2. Accountability of medicines and MP in the hospital departments.
3. Accountability of medicines and MP at the post (in procedure rooms).
4. Accounting of medicines and MP.

They were studied together with the inherent properties for MPI. Regarding inventory control of medicines and MP it should be noted that this part of accounting provides a well-timed and accurate accounting treatment of operations on their receiving, transfer and disposal. At this stage accountability is performed for each drug name separately, indicating its name, dosage, form of presentation, information concerning packaging, the name of drug manufacturer, quantity, price, and amount. These data are recorded in writing in the special books of a definite form in accordance with the legislation. According to the physicochemical properties of drugs the storage conditions are also determined. And according to their pharmacological groups their storage is carried out. At this stage medicines and MP are delivered to the department in accordance with requisitions of a nurse supervisor with indication of the actually delivered quantity with respect to each product, price and amount. The materially responsible person is accountable monthly to the Accounting Department of MPI for distribution of medicines and MP based on these invoices [2, 5, 8].

The next stage of the way of medicines and MP is in the hospital departments. Their accounting is conducted by materially responsible persons of the departments in writing in accordance with the applicable law for each drug name in quantitative terms. In addition, this phase provides the compliance of requirements regarding the conditions of storing medicines and MP; the timely bringing on charge the medicines and MP received from the warehouse and their delivery to the posts (procedure rooms); compliance with deadlines concerning preparation of reporting for medicines and MP (their receiving the warehouse, delivery to the posts (procedure rooms) and use) and well-timed reports submitted by the departments to the Accounting Department of MPI [3].

The final stage of accountability of medicines and MP within MPI is medical posts and procedure rooms. At this stage distribution is mainly carried out by nurses of the departments in accordance with the doctor's prescriptions to the patients and is recorded in writing in a definite form. The report on receiving and use of medicines and MP is given to the head (supervisor) nurse of the department at least once a month [9].

In addition to the analytical accounting of medicines and MP in healthcare institutions the book-keeping is also carried out. It is conducted in accordance with unified methodological principles of the law of Ukraine dated 16.07.1999 №996-XIV "On book-keeping and financial reporting in Ukraine" considering the specific accounting for budget organizations. For this purpose most MPI use computer technologies with standard software application individually developed for each healthcare institution taking into consideration the number of hospital beds and specialties. The accounting is conducted in the value and quantitative form; recording is common, but each MPI is allowed some variations within the legislation, for example to choose a method of disposal on their own. Periodically the accounting department conducts an inventory of medicines and MP, and it affects simplification of monitoring for their way at all accounting stages in MPI [10].

CONCLUSIONS

The analysis conducted shows that the current legal regulation of medicines and MP under the conditions of MPI generally covers the whole range of measures to their distribution. The way of medicines and MP from their receiving in MPI to their use by the patient is clearly observed. To conduct the analysis the components, namely inventory control of medicines and MP; accountability of medicines and MP in the hospital departments; accountability of medicines and MP at the post (in procedure rooms), accounting of medicines and MP, have been identified. The role of each component in implementing the entire process of accountability has been studied.

REFERENCES

1. *Law of Ukraine "Fundamentals of the legislation of Ukraine on Healthcare" of 19.11.92 №2801 // VVR. – 1993. – №4.*
2. *Law of Ukraine "On Medicines" of 04.04.96 №123/96 – VR // VVR. – 1996. – №22.*
3. *Muzika T.F. // Ukr. J. of Neuropsychiatrist. – 2009. – Vol. 17. – P. 174-175.*

4. *The law of the Ministry of Health of Ukraine dated 19.07.2005 №360 "On approval of prescribing and order requirements for medicines and medical products. Dispensing of medicines and medical products in pharmacies and their subdivisions. Instruction regarding storage, recording and disposal of prescription forms and order requirements" [Electronic resource]. – Access: <http://www.zakon.rada.gov.ua>.*
5. *The law of the Ministry of Health of Ukraine dated 16.12.2003 №584 "On approval of storage rules and the quality control of medicines in medical and preventive institutions [Electronic resource]. – Access: <http://www.zakon.rada.gov.ua>.*
6. *The law of the Ministry of Health of Ukraine dated 21.01.2010 №11 "On approval of procedures for distribution of narcotic drugs, psychotropic substances and precursors in healthcare institutions of Ukraine" [Electronic resource]. – Access: <http://www.zakon.rada.gov.ua>.*
7. *The law of Ministry of Health of Ukraine dated 09.09.2014 №635 "On approving the Guidelines for accountability of medicines and medical products in medical and preventive institutions" [Electronic resource]. – Access: <http://www.zakon.rada.gov.ua>.*
8. *The law of the Ministry of Finance of Ukraine dated January 10, 2007 №2 "On approving the Guidelines for accounting the reserves approved for budgetary institutions, organizations" [Electronic resource]. – Access: <http://www.zakon.rada.gov.ua>.*
9. *Tolochko V.M. // Continuing Education for pharmacy specialists in organizational and economic direction. – 2010. – P. 47-48.*
10. *Tolochko V.M. // Medical and Social Ecology of Personality: State and Prospects. – 2010. – P. 86-88.*

АНАЛІЗ НОРМАТИВНО-ПРАВОВОГО РЕГУЛЮВАННЯ ОБЛІКУ ЛІКАРСЬКИХ ЗАСОБІВ І ВИРОБІВ МЕДИЧНОГО ПРИЗНАЧЕННЯ В ЗАКЛАДАХ ОХОРОНИ ЗДОРОВ'Я

Т.Ф.Музика, М.В.Зарічкова, М.В.Чешева

Ключові слова: фармацевтичне забезпечення; лікувально-профілактичні заклади; лікарські засоби; виробництво медичного призначення; обіг; облік

Досліджено нормативно-правове регулювання обігу та обліку лікарських засобів (ЛЗ) і виробів медичного призначення (ВМП) в закладах охорони здоров'я, виявлені його особливості, притаманні саме для лікувально-профілактичних закладів (ЛПЗ). У ході проведення досліджень було встановлено, що саме підлягає предметно-кількісному обліку в ЛПЗ, виділено перелік облікових операцій під час проходження ЛЗ і ВМП (приймання, зберігання, відпуск (переміщення), списання). Проаналізовано обліковий процес ЛЗ і ВМП від отримання їх у ЛПЗ до пацієнта та виявлено необхідність його розподілу на декількох складових, а саме: складський облік ЛЗ і ВМП; облік ЛЗ і ВМП у відділеннях ЛПЗ; облік ЛЗ і ВМП на постах (у маніпуляційних кімнатах); бухгалтерський облік ЛЗ і ВМП. Встановлено, що кожна складова виконує окреме завдання для дотримання умов зберігання, термінів придатності, контролю за використанням та звітності. Встановлено, що окрім аналітичного обліку в ЛПЗ ведеться й бухгалтерський облік, який в межах чинного законодавства адаптований для бюджетних організацій. Проведений аналіз показав, що сучасне нормативно-правове регулювання обігу ЛЗ і ВМП в умовах ЛПЗ в цілому охоплює весь комплекс заходів з їх обігу. Встановлено, що недотримання певних заходів з цих питань унеможливує контроль усього шляху проходження ЛЗ і ВМП від отримання їх лікувальним закладом до використання пацієнтом.

АНАЛИЗ НОРМАТИВНО-ПРАВОВОГО РЕГУЛИРОВАНИЯ УЧЕТА ЛЕКАРСТВЕННЫХ СРЕДСТВ И ИЗДЕЛИЙ МЕДИЦИНСКОГО НАЗНАЧЕНИЯ В УЧРЕЖДЕНИЯХ ОХРАНЫ ЗДОРОВЬЯ

Т.Ф.Музыка, М.В.Заричковская, М.В.Чешева

Ключевые слова: фармацевтическое обеспечение; лечебно-профилактические

учреждения; лекарственные средства; изделия медицинского назначения; оборот; учет
Исследовано нормативно-правовое регулирование оборота и учета лекарственных средств (ЛС) и изделий медицинского назначения (ИМН) в учреждениях здравоохранения, установлены их особенности, характерные именно для лечебно-профилактических учреждений (ЛПУ). В ходе проведения исследований было установлено, какие именно группы ЛС подлежат предметно-количественному учету в ЛПУ, выделен перечень учетных операций во время прохождения ЛС и ИМН (прием, хранение, отпуск (перемещение), списание). Проанализирован учетный процесс ЛС и ИМН от получения их в ЛПУ до выдачи пациенту и выявлена необходимость его распределения на несколько составляющих, а именно: складской учет ЛС и ИМН; учет ЛС и ИМН в отделениях ЛПУ; учет ЛС и ИМН на постах (в манипуляционных комнатах); бухгалтерский учет ЛС и ИМН. Установлено, что каждая составляющая выполняет отдельное задание по соблюдению условий хранения, сроков годности, контроля за использованием, отчетностью. Выяснено, что кроме аналитического учета в ЛПУ ведется и бухгалтерский учет, который в рамках действующего законодательства адаптирован к деятельности бюджетных организаций. Установлено, что невыполнение определенных мероприятий по этим вопросам исключает возможность прослеживания всего процесса прохождения ЛС и ИМН от получения их лечебным учреждением до использования пациентом.