Internal Audit in the Pharmaceutical Sector: International and National Good Practices

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Abstract

Internal audit plays an increasingly important role in the field of management. In today's economic environment, means and methods to achieve high financial performance in the medium and long-term perspective are purposefully sought.

In the new reality, practice puts an emphasis on the need for additional control on the activities which, in turn, justifies concrete changes in the policy of the organizations as well. In terms of the individual organization, the implementation of internal audit is a set of applications of international practices and compliance with the national legislation that are undertaken to improve the competitiveness.

Key words: internal audit, good practices, pharmaceutical sector
JEL: F53, I18, M42

Introduction

The historical origin of the audit is linked **to the birth of statehood** and the accompanying government control on the activities and the accountability of organizations. Its participation has been limited to verification and prevention of accounting errors and compliance with the tax regime.

The need of an internal audit is associated with an increase in the size of the organization and the scope of its activities. Since 19 century, organizations have created more complex structures with widely dispersed geographic locations. The limited ability of the management to monitor all structural units and business activities has led to constituting the internal auditing as a monitoring function.

With the expansion of production and distribution of medicinal products beyond the national borders, in 1967 the internal audit **was separated** as an activity from the external audit[1]. In the "Good Manufacturing Practice" of the World Health Organization, the internal audit is presented as part of the quality control of medicinal products. Considering the social and economic significance of the pharmaceutical sector, most countries adopt national policies for medicinal products according to which the manufacturers are required to adopt a quality assurance system, including an internal audit. Manufacturers of medicinal products have the right to exercise control over suppliers of raw materials and over distributors, and to this end, the latter create new structural internal audit units.

For historical and legislative reasons, the internal audit is not yet a subject of the academic periodicals[2]. The functions of the audit for the organization and for the society determine the literature as regulation interpretative. Due to the different stages of development of the national economy and the lack of a uniform structure of the individual organizations, **the literature is limited to manuals from international organizations and national laws** and with a small focus on empirical data. The study of the internal audit is a field wider than its nature, as defined by the Institute of Internal Auditors[3].

Approximation of International Good Practices in Internal Audit

The process of globalization puts on the agenda the product quality issue. To occupy competitive positions on the international market, organizations are beginning to use a **new management tool** – internal audit. Its separation from the external audit is accompanied by scientific debate and governmental support. The scope of internal audit is expanding, as the traditional function of control over accounting is complemented with new fields, such as verification of the financial management and quality management. The internal audit begins to provide a service for the management.

As the beginning of the process of approximation of the internal audit policies is to be accepted the crisis in 2002 in USA (Enron, WorldCom). Violations of accounting standards and the lack of good audit practices create regulatory

[1] World Health Organization. WHO Good Manufacturing Practices for Pharmaceutical Products: Main Principles. Technical Report Series, No. 961, 2011.
[2] Swinkels, W. Exploration of a theory of internal audit. University of Amsterdam, 2012.
[3] Sarens, G., I. de Beelde. The Relationship between Internal Audit and Senior Management: A Qualitative Analysis of Expectations and Perceptions. International Journal of Auditing, 10, 2006, p. 219.

requirements for the building and the efficient functioning of good internal audit practices on a world scale[4].

Approximation of international policies on internal audit is carried out in three different directions:

- Being the result of the processes in international economic relations, the **policies on quality** in the various regions of the world have marked convergence. The internal audit in the pharmaceutical sector expands its field of action to include control of the quality system. In the "Pharmaceutical Quality System Guidance" (ICH Q10), adopted in the EU, Japan and the US, the quality system requirements provide a "feedback on the quality of the production of internal and external sources, non-conformity of the established parameters, discontinued sales, deviation from standards, results of auditors and inspections by regulatory authorities". In the EU, self-inspection is part of the quality system, while in the US and Great Britain the broader term is used - "internal audit".

- **The approximation of accounting standards** determines the convergence of the auditing standards. The Norwalk Agreement of 2002 between the International Accounting Standards Board and the US Financial Accounting Standards Board provides for integration of the accounting standards. Additional trend is approximation of the audit practices in order to ensure that the financial reports comply with the International Accounting Standards.

- Globalization of organizational assets and capital markets places on the international community's agenda the debate on the various practices in **risk management**. On expanding their activities abroad, pharmaceutical organizations are beginning to apply similar criteria in accordance with the national requirements. The control of risk management, as part of the scope of the internal audit, is applied under the "bottom-up" scheme - good practices of leading organizations are recorded by the supervisory authorities and are adopted by the remaining organizations.

Regardless of the approximation process, policies on internal audit should consider in perspective the general problem of the structural control departments (internal audit, risk management, IT risk) which are located in the middle management level of the organization. Typically for the approximation of the international practices, the internal audit finds the **balance between the requirements of the supervisory authorities and the expectations to add value to the organization**. The internal audit must be functionally separated from the daily management, but also to provide opportunity for the top management to ensure that their recommendations have corrective action.

The contemporary practice solves the issue by diversifying the internal audit teams. Their composition is intersectoral and interfunctional, and includes experts in accounting, finance, risk management, information technology, and investment.

EU Common Practices

The EU policy in respect of the medicinal products is **protection of the interests of the citizens and the economy**. The system for admission to the market must ensure that all medicinal products are evaluated by a competent authority for compliance with the requirements for safety, quality, and efficiency. One of the tools of the system is carrying out an internal audit.

The EU internal audit practices originate from the Euro Model for Excellent (EFQM Excellence Model). It was adopted in 1991 in response to changes in the external environment and most of all due to the increased competition of the United States and Japan. The Euro Model establishes a framework for evaluation and improvement of the European organizations for competitiveness.

Individual states are beginning to apply internal audit in their national legislation. Good practices for the EU include the two main stages of the pharmaceutical sector: Production (Directive 91/356/EEC on the principles and guidelines of good manufacturing practice for medicinal products for human use) and distribution (Directive 92/25/EEC on the wholesale distribution of medicinal products for human use).

The process of harmonization in the EU provides **regulation** of good practices in production, while distribution practices remain **priority of the manufacturers themselves**. The contemporary EU policy is laid down in the "Guidelines on Good Manufacturing Practice"[5] of the European Commission.

Good Practices in Bulgaria

With the adoption of the market principles and the fall of the state monopoly in the pharmaceutical sector, the international good practices for the production and distribution of medicinal products have begun to apply in Bulgaria. The scope of activity of the internal audit is expanding, as the traditional accounting activity is complemented by quality management.

In 1995, the first law regulating the pharmaceutical sector was passed - the Law on Medicines and Pharmacies in Human Medicine. Its 2000 amendment reviews solely the good manufacturing practice as a system of rules which covers all aspects of production.

[4] Institute of Internal Auditors. The role of the internal control and the function of the internal audit for the effective management and organic growth of the organizations. 2006.

[5] European Commission. Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use.

Since 2001, through the "Good manufacturing practice of medicines", the requirements of the World Health Organization have been applied (Ordinance No. 12 of 03.26.2001 for the establishment of the good manufacturing practice of medicines, the State Gazette, issue 47, 2001). In accordance with the European practice, the internal audit is considered as "self-inspection".

Since 2007, Ordinance No 39 has reviewed the good distribution practice as part of the quality system which ensures adequate control at all stages of the process of wholesale trade in medicinal products. At the root of the good distribution practice lies the principle for sharing the responsibility for quality and safety of medicinal products. The Ordinance envisages the legal opportunity and obligation to carry out audits in the own organization, as well as in that of the suppliers and distributors. Responsibility for conducting the audit is shared between manufacturer, supplier and distributor, i.e. the manufacturer has the legal opportunity to carry out internal audits of suppliers and distributors from the time of receipt of the authorization for production, and on a periodic basis.

In 2009, Ordinance No 15 introduced the provisions of Directive 2003/94/EC on good manufacturing practices. The good manufacturing practice for medicinal products is subject to the principles of sharing the responsibility for the quality, safety and efficacy of medicinal products. The internal audit is specified in an amendment to the Ordinance of 2013, as the manufacturers of medicinal products have been assigned with the responsibility to establish and maintain a department of quality control functioning under the management of a person who has the requisite classification and is independent from the production. The manufacturer is obliged to conduct periodic self-inspections and control within the framework of the quality assurance system for the purposes of monitoring the application of the principles of good manufacturing practices and the implementation of the necessary corrective measures.

A tendency towards changes in the scope exists in the contemporary Bulgarian practice of internal audit[6]. The focus of work is expected to shift to audits of processes and in particular to corporate governance, information technology, risk management, and ethics. The role of internal audit reports a change towards increasing the role of the internal audit in relation to the risk management in the company.

Conclusion

In the modern economy, there is a trend towards **introducing new tools** to the management, and also **using traditional tools in a new way**. The internal audit is exactly such a tool: for countries with established market economy, it is a traditional tool with a new application, while for Bulgaria it is a new tool. The effects of the global crisis and the requirements of the European directives determine the internal audit as one of the main tools of the management for competitiveness and economic growth.

The specifics of internal audit are determined by the processes in the world economy. A key factor in determining the practice of internal auditing is the globalization. To increase the competitiveness, the internal audit becomes a mandatory element in the organizations introduced by the good practices. The current internal audit practices are being influenced mainly by processes at three separate levels: international, pan-European and national level.

The approximation of international internal audit policies is carried out in accordance with definitions and recommendations of international organizations. The process of globalization creates requirements for control of the quality system, approximation of audit standards in parallel with approximation of accounting standards and risk management.

Harmonization of the internal audit rules in the EU stems in a regulatory order harmonized with the recommendations of the international specialized organizations. Directives are used to establish the institutional framework for competitiveness and a single definition for independence of auditors.

The Bulgarian practice follows the dynamics of European trends. With the accession of Bulgaria to the EU, the internal audit units were created. The Directives are applied through the "Good Manufacturing Practice" Standard.

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