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FEATURES OF INTERNAL AUDIT IN PHARMACEUTICAL INDUSTRY

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Abstract. The review highlights the main features of internal audit by focus on distribution of medicinal products. Recent data suggest internal audit as an antidote to effects of economic recession. The present review reveals internal audit as a tool for competitiveness through implementation of good practices.

The purpose of the review is to describe the advantages of internal audit in new institutional frame. The object of analysis is the distribution practice, and more concrete, the wholesale distributors. The analysis was perform by factor analysis and done in response to the tendency for outsource of distribution activities and practical interest in the use of internal audit by implementation of requirements and recommendations for good practices.

The results showed that the internal audit in pharmaceutical industry is determinate by two factors: regulatory requirements and complexity of supply chain. The external and the internal environment define five features of internal audit in pharmaceutical industry.

Keywords: internal audit, good practices, medicinal products.

Introduction

Internal auditing is an independent, objective assurance and consulting activity designed to add value and improve an organization's operations [1]. According to regional legislations, the internal audit is defined for EU members as “self-inspection” [2] and as “measurement, analysis and improvement” according to ISO 9000:2000 [3]. The process of internal audit is carrying out by a distributor on its own systems, procedures and facilities [4]. The distributor employs the internal auditor.

The reason for providing of internal audit is either legislation requirements or decision by management. The legislation requirements are based on standards described in ISO and good practices. The management must define audit agenda on fixed time or extraordinary. The target of audit activity should be verification of quality system and compliance with laws and regulations. The business benefits for the distributor are benchmarking and recommendations for corrective measures to achieve their stated objectives.

At micro level, internal audit is organized depend on the size, structure and complexity of distributor’s organisation and activities. At macro level, there are different standards and regulations against which the distributor to be assessed.

Distribution is an important part in supply chain of medicinal products [5]. The purpose of internal audit is compliance with requirements at every level. The complexity of supply process with medicinal products contains various stages with its own good practices:

- at development stage complying with Good Clinical Practice [6] and Good Laboratory Practice [7];
- at manufacturing stage – Good Manufacturing Practices (GMP) [8];
- at distribution stage – Good Distribution Practice (GDP) [9].

In supply chain, the distributors shall carry on self-inspections for compliance with GDP while the competent authorities inspect distributors for compliance with GMP [10]. Regardless of the competent authority and time of accepting, every good practice provides existence of internal audit as managerial tool for safety, quality and efficacy of medicinal products.

World Health Organization (WHO) introduced the first version of GMP in 1967. Based on WHO guidelines many countries (EU, US) and organizations (International Standard Organization, International Conference on Harmonization) developed their own guidelines [11]. GMP standards were harmonized in EU since 1991 and at supranational level

(International Conference on Harmonization is a common project of EU, US and Japan) since 1999.

GMP is mandatory for introduction for the manufacturers of medicinal products, but the addition of ISO 9001 to the already established GMP-system creates a better management of the system and provides additional benefits. The ISO standards represent an international consensus on good management practices instead of mandatory requirements by EU Directives. In EU, the ISO standards have been transposed as national standards by the national standards institutes, which are members of the European standardization bodies (CEN and CENELEC). The EU standards (EN ISO) are referred to some specific harmonization Directives.

The ISO standards play an important role in the European Union's industrial policy, both in relation to the promotion of the competitiveness of European industry, and with regard to the free movement of goods [12]. Adoption of ISO's good practices in EU aims to comply with customers who require ISO certificate; to improve competiveness; to minimize repetitive auditing by similar and different customers, and to improve subcontractors' performance.

The additional advantage for manufacturers to adopt ISO 9001 is a management advantage over those who had not adopted the international quality management standard [13]. The introduction of ISO 9001 is a benefit to GMP by measurement of customer satisfaction. Simultaneous introduction of ISO 9001 and GMP is a benefit for lowest manufacturing expenditures.

The distribution of medicinal products in Bulgaria is regulated by national legislation (Laws and Regulations) [14]. In addition, relevant EU documents (Directives, Regulations, and Guidelines) are also applicable. For import from non-EU countries, the wholesaling companies should comply with WHO Good Distribution Practice for pharmaceutical products.

The GMP is described as a shared responsibility for quality, safety and efficacy of medical products (Regulation № 15 of 17.04.2009). The base of Bulgarian practice is the principles of EU GMP. The self-inspection is manufacture/importer responsibility for periodical control over implementation of GMP.

The GDP is stated as a part of the quality system (Regulation No. 39 of 13 September 2007 on the Rules and Requirements for the Good Distribution Practice by Ministry of Health). The base of GDP is a shared responsibility of quality and safety of the medicines.

Materials and Methods

The object of study is internal audit in wholesale distributors of medicinal products. The paper aims to review the existing good practices on the application of internal audit especially to improve quality control and to competitive power. We have used official sources - recommendations by international organizations, EU Directives for common policies and requirements by national legislation. The data analysis shows that the good manufacturing practice is an international matter while the good distribution practices – pan-European and national matter.

Results

By using of the factor analysis, we reveal two main factors for internal audit features: industry characteristics and distributor's organization.

The role of pharmaceutical industry defines the features of internal audit

The features of internal audit are influence by growth opportunities due to advances in technology, the expansion of communication capabilities and the increasing complexity and sophistication of global business operations [15]. The current economic recession puts internal audit in agenda in pharmaceutical industry for competitive power and economic growth. The recession increases expenditures for internal audit activities and decreases expenditures for analysis.

The key role of pharmaceutical industry for society and national economy leads to requirements at every stage in the supply chain. From microeconomics point of view, the pharmaceutical industry is main element for the public health and needs of innovative and safety medicinal products on acceptable prices [16]. From macroeconomics point of view, the pharmaceutical industry is a strategic pillar for economic growth, employment and competitiveness.

The complexity of pharmaceutical industry is higher than in rest industries due to overseas distribution and outsourcing of activities. The characters of the industry define the features of his internal audit: compliance with legislation, public health and safety, transparent procedures for pricing and reimbursement, intellectual property rights.

The characteristics of industry are relevant to features of internal audit practices. The stronger requirements by regulator for some industries lead to increasing of investment in internal audit. Social important industries, such as financial and utilities are highly regulated [17]. Additionally, the pharmaceutical industry is highly regulated also and as distinguished from other industries, the regulators are from different industries and different legislations [18].

The size and complexity of the distributor define the features of internal audit

The size and structure of the distributor reflect on quality system and internal audit activities. Large distributors are more vulnerable to institutional pressures due to their prominent role in society [19]. The complexity of organization defines broader scope and larger staff for internal audit activities. The raising the standard of ISO 9001 requirements add high costs for small and medium sized enterprises to implement the new version and cancel out the added value they may derive from it [20].

Discussion

Regulatory requirements for compliance with legislation, market pressure for implementation of guidelines for GDP and managerial expectations for corrective measures define the following features of internal audit in pharmaceutical industry:

- *Independence and objectivity*. The internal audit shall be separate from other functions and activities of the distributor. The internal audit activities are independent of management and without undue influence. The independence is limit to the manager, whose sphere of authority it may audit and from the activities subject to audit. The internal auditor should report to the board and propose necessary corrective measures. The internal audit department must have sufficient financial resources and staff with the necessary skills to achieve monitoring for implementation and compliance with GDP.

Directive 2003/94/EC laying down the principles and guidelines of GMP in respect of medicinal products for human use and investigational medicinal products for human use. The self-inspection is a part of quality assurance system in order to monitor the implementation and respect of good manufacturing practice and to propose any necessary corrective measures.

GDP is described in Directive 2001/83/EC, Directive 2004/27/EC, and EU Guidelines on Good Distribution Practice of Medicinal Products for Human Use (2013/C 343/01). The aim of self-inspection is ensuring of maintaining the level of quality determined by throughout the distribution network.

- *Scope and frequency*. The internal audit covers all aspects of GDP.

The scope and frequency of the audit shall be clearly defined in an audit programme. The annual audit programme, approved by the board and external auditor, contains both fixed time and extraordinary inspections. Each business unit, supplier and subcontractor should be inspected once during the year. The minimum frequency for inspection is at least annually.

The scope of internal audit within a defined period is compliance with regulations, guidelines and operating procedures. The internal audit process for complex distributors may be divided into several individual processes with limited scope. For example, in details - “internal audit of overseas warehouses”, or in general - “assessment of contract for transportation”.

The scope of extraordinary audit is limited both for activities and for products. The

extraordinary audit should be carry on in case of complaints, returns, suspected falsified medicinal products recalls.

- *Approach*. The internal audit activity evaluates and improves the effectiveness of processes by a systematic and disciplined approach. The audit manager designs the approach from clearly established objectives, scope and criteria. The internal audit role for determining the mistakes qualify the proactive approach as most using approach. The independence, focusing on details and broad scope are characteristics of internal audit due to complexity of pharmaceutical industry. In case of complex supply chain, the distributor carry on audit by principles of shared responsibility approach for safety and quality medicinal products [21].

- *Staff*. Internal audit is carrying out from experts nominated by the management under requirements of ISO 9001: 2008 Quality management systems (6.2). The organization shall issue and maintain documented procedures for Internal Audits (8.2.2). The standard uses an approach for effective issues, rather than execution of formally prescribed issues. The guidance on auditing management systems is provided by ISO 19011: 2011.

The internal auditor is a part of company management and paid by the distributor. For small and medium distributors is recommended to hire an internal auditor outside the staff. The external auditor may not be used as a substitute for internal auditor.

The internal audit should be conducted by designated competent person from the company who is indirectly involved and without charges to inspected object. The competency includes broad study fields, universality, and professional ethics. There are not requirements for knowledge, education and experience in pharmaceutical fields.

- *Administrative procedures*. The volume of documentation is determined by the scope of inspection. Distributors' organization for documents processing constitutes an essential part of the quality management system.

All inspection results should be recorded [22]. The record should contain the observations and proposals for corrective measures, where applicable. The report should be provided to the board and be retained for a period not shorter than 5 years [23].

The board should evaluate the inspection report and taken corrective actions, if any. Where necessary, shall be taken corrective action, including a follow-up audit of deficiencies [24]. The corrective and preventive action should be carry on with the principles of quality risk management.

Conclusion

Our results suggest that the features of internal audit are defined both by characteristics of the industry and the distributor. The key role and complexity of pharmaceutical industry lead to high expectations for internal audit activities. The size and structure of the distributor reflect on internal audit activities.

Further study on internal audit is needed to reach the better conclusion. A comparative analysis by interviews with board members to reveal legislation requirements and managerial practices is highly recommended.

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